IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 4:24-cv-00953-P

Appendix (Vol I of IV) in Support of Plaintiffs' Motion for a Preliminary Injunction and Stay Pending Review

Certificate of Service

I hereby certify that a true and accurate copy of the foregoing document was filed electronically (via CM/ECF) on January 28, 2025, and that I caused a copy of the foregoing, and all accompanying papers, to be served via process server and via U.S. mail on the following:

United States Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, Maryland 20903

Dated: January 28, 2025

/s/ Ty Doyle

TY DOYLE (Texas Bar No. 24072075)
BAKER & HOSTETLER LLP
811 Main Street, Suite 1100
Houston, TX 77002
(713) 646-1374
tgdoyle@bakerlaw.com

Attorney for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION; NORTH AMERICAN CUSTOM LABORATORIES, LLC D/B/A FARMAKEIO CUSTOM COMPOUNDING, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Civil Action No. 4:24-cv-00953-P

Declaration of Dan DeNeui

Pursuant to 28 U.S.C. § 1746, I, Dan DeNeui, declare as follows:

1. I am the Chief Executive Officer and Managing Partner of North American Custom Laboratories, LLC d/b/a FarmaKeio Custom Compounding ("FarmaKeio"). I submit this Declaration in support of Plaintiffs' motion for a temporary restraining order and preliminary injunction. I have personal knowledge of the facts stated herein.

2. FarmaKeio is a Texas limited liability company headquartered in Southlake, Texas.

3. FarmaKeio owns and operates a compounding pharmacy in Richardson, Texas, that is regulated under Section 503A of the Food, Drug, and Cosmetics Act.

4. FarmaKeio's compounded prescriptions are prepared in a state-of-the-art facility designed to ensure the highest level of safety, potency, and efficacy.

5. FarmaKeio provides custom compounded prescriptions for a variety of health needs including weight loss, thyroid and adrenal support, hormone therapy, autoimmune/naltrexone, cognitive function, sleep, sexual health, hair loss, gut health, and energy.

Patients Turn to Compounding Pharmacies To Fill Tirzepatide Prescriptions

6. Tirzepatide is the active ingredient of FDA-approved prescription drugs that treat type-2 diabetes and obesity. Tirzepatide is administered via injection and sold under the brand names Mounjaro for diabetes treatment and Zepbound for weight loss. Tirzepatide has been proven effective and is in exceptionally high demand.

7. When the FDA listed Tirzepatide on the Section 506E shortage list in December 2022 ("Drug Shortage List"), compounding pharmacies like FarmaKeio began producing Tirzepatide to satisfy demand and patient needs with compounded version of the drug.

8. As part of my role at FarmaKeio, I routinely evaluate market conditions for the products we provide patients. Demand for compounded Tirzepatide has remained at exceptionally high levels through the month of January 2025.

9. Patients and medical providers report that compounded versions of Tirzepatide are generally as effective as Zepbound and Mounjaro.

FarmaKeio's Tirzepatide Compounding Business

10. Until December 19, 2024, Tirzepatide was listed on the FDA's Drug Shortage List. Relying on that listing, FarmaKeio compounded Tirzepatide to ensure that patients would have access to necessary medical care.

11. FarmaKeio began compounding Tirzepatide in January 2023.

12. FarmaKeio compounds Tirzepatide at its facility in Richardson, Texas.

13. Thirty employees work at this FarmaKeio facility.

14. FarmaKeio compounded approximately 67,134mL of Tirzepatide in the fourth quarter of 2024, which (given the varied weekly dosing of Tirzepatide) supplied approximately 25,097 patients.

FDA Abruptly Removes Tirzepatide from the Drug Shortage List

15. On December 19, 2024, the FDA again removed Tirzepatide from the Drug Shortage List (the "Delisting Action").

16. Patients continue to report shortages of Tirzepatide.

17. The FDA's action restricts FarmaKeio's ability to continue compounding Tirzepatide—in particular, drug products that are essentially copies of commercially available Tirzepatide. With Tirzepatide removed from the Drug Shortage List, FarmaKeio will be unable to continue accepting prescriptions for Tirzepatide and filling them with compounded Tirzepatide. FarmaKeio would continue accepting prescriptions and filling them with compounded Tirzepatide but for FDA's action.

18. If the FDA's decision to delist Tirzepatide from the Drug Shortage List remains in effect, FarmaKeio will be forced to permanently cease its Tirzepatide compounding business.

19. FarmaKeio will suffer approximately $1,750,000-$2,000,000 in lost revenue per month as a consequence of the FDA's Delisting Action.

20. The FDA's Delisting Action, if it remains in effect, will cause FarmaKeio to lay off 6-9 employees.

21. If the FDA's Delisting Action remains in effect, the patients that FarmaKeio currently serves will be unable to get their Tirzepatide prescriptions filled by FarmaKeio.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on the 28th day of January, 2025.

/s/ Dan DeNeui
Dan DeNeui

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 4:24-cv-00953-P

Declaration of Andrew M. Grossman

I, Andrew M. Grossman, declare as follows under 28 U.S.C. § 1746:

1. I am above the age of 18 years, have personal knowledge of the matters set forth below, and am in all respects competent to render this Declaration.

2. I am a Partner of the law firm of Baker & Hostetler LLP and am counsel for Plaintiffs Outsourcing Facilities Association, et al.

3. I submit this Declaration in support of Plaintiffs' Memorandum in Support of a Preliminary Injunction and Stay Pending Review

4. A true and correct copy of the FDA's December 19, 2024 redacted Decision is attached as Exhibit 1.

5. A true and correct copy of the FDA's December 19, 2024 Order is attached as Exhibit 2.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 28th day of January, 2025.

/s/ Andrew M. Grossman
Andrew M. Grossman

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION, et al. Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al. Defendants.	Civil Action No. 4:24-cv-00953-P

Declaration of Lee Rosebush

Pursuant to 28 U.S.C. § 1746, I, Lee Rosebush, declare as follows:

1. I am the Chairman of the Outsourcing Facilities Association, and I have personal knowledge of the facts stated herein.

2. The Outsourcing Facilities Association (OFA) is the trade association representing FDA-registered 503B outsourcing facilities who focus on providing patients and healthcare providers with safe and effective compounded medications. Every OFA member is an outsourcing facility or affiliate that operates under Section 503B of the Federal Food, Drug, and Cosmetic Act ("FDCA"). OFA members work with patients, healthcare providers, and facilities on a daily basis to ensure the specific needs, of both providers and patients, for compounded medications are satisfied. OFA will continue to work with industry, governmental agencies, and healthcare providers to educate and advocate for outsourcing facilities and the critical need to ensure that patients and providers have access to the medications they need.

3. As the Chairman of OFA, I run the day-to-day operations of the largest trade association for FDA registered 503B outsourcing facilities. Until December 19, 2024 Tirzepatide was listed on the FDA's Drug Shortage List. Relying on that listing, OFA members compounded Tirzepatide to ensure that patients would have access to necessary medical care.

4. As part of my role at OFA, I regularly correspond and confer with OFA members about their operations and have in-depth personal knowledge about how outsourcing facilities are run, produce products, and satisfy legal standards. I also regularly correspond and confer with FDA. I also routinely review a wide range of sources to evaluate supply and demand for drugs like Tirzepatide, which is the active ingredient of FDA-approved prescription drugs that treat type-2 diabetes and obesity. Tirzepatide is administered via injection and sold under the brand names Mounjaro for diabetes treatment and Zepbound for weight loss. Tirzepatide has been proven effective and is in exceptionally high demand. A true and correct copy of CNBC's December 11, 2024 article "Ro to offer lower-price vials of weight loss drug Zepbound by teaming up with Eli Lilly" is attached as Exhibit 13 and was submitted by OFA to FDA on December 13, 2024.

5. Additionally, in my role at OFA, I interact from time to time with representatives of the Food and Drug Administration ("FDA"), including on issues of drug shortages. I understand that FDA employees monitor the same sources of information that I do and must be aware of the information reported in those sources. I have found these sources to provide reliable information on drug availability, among other things. If in fact FDA officials and employees are not monitoring publicly available sources of information about drug shortages, that would be equivalent to regulatory malpractice.

6. Based on my review, I have determined that the Tirzepatide shortage has not resolved since FDA sought a voluntary remand in October 2024 to reconsider its decision resolving

the Tirzepatide shortage. Further, I have concluded that the shortage will be exacerbated should compounders not be able to compound Tirzepatide copies. Exhibit 40 is a true and correct copy of recent data submitted by OFA to FDA demonstrating continued supply shortages into January 2025.

Compounding Pharmacies Fill Many Tirzepatide Prescriptions

7. Compounding under Sections 503A and 503B serves vital national interests, especially in the case of drug shortages. When a drug is on the drug shortage list, compounding pharmacies operating under Section 503A may compound forms of the drug that are essentially copies of FDA-approved forms of the drug, which is otherwise generally prohibited. When a drug is on the drug shortage list, outsourcing facilities operating under Section 503B may compound forms of the drug (including copies) that are otherwise generally unlawful to produce, except in narrow circumstances that do not apply to Tirzepatide.

8. The listing on FDA's drug shortage list enabled pharmacies and outsourcing facilities to satisfy demand and patient needs through compounding, including of drugs that are essentially copies of FDA-approved versions of Tirzepatide.

9. When the FDA listed Tirzepatide on the Section 506E shortage list in December 2022, compounding pharmacies began producing Tirzepatide to satisfy demand and patient needs with compounded version of the drug. I conferred with numerous OFA members and learned that they devoted manufacturing lines and substantial resources to filling the nationwide Tirzepatide shortage.

10. Compounding activities by outsourcing facilities require significant investment and lead time before facilities can achieve profitability. Facilities must allocate manufacturing lines to compounding a given drug, which would otherwise be available for other product production.

Facilities must also spend money on research, development, and compliance, as well as ingredients. Generally speaking, it takes hundreds of thousands of dollars and approximately 6-9 months of lead time for an outsourcing facility to begin compounding and distributing a drug like Tirzepatide. Profitability is achieved sometime after that.

11. Patients report that compounded versions of Tirzepatide are generally as effective as Zepbound or Mounjaro. A true and correct copy of Change.org Petition "Protect Patients: Demand the FDA Ensure Access to Affordable GLP-1 Medications!" as of December 18, 2024 is attached as Exhibit 17 and was submitted by OFA to FDA on December 18, 2024. These reports comport with my personal knowledge of the efficacy of compounded forms of Tirzepatide.

12. CBS News reported that some patients are finding compounded Tirzepatide to be one-third the cost of Zepbound. Exhibit 36 is a true and correct copy of the CBS News article.

13. Compounding pharmacies fill prescriptions for millions of patients. Exhibit 37 is a true and correct copy of a CBS News article reporting "that several large compounding pharmacies…are provisioning up to 2 million American patients with regular doses of semaglutide, the scientific name for Novo Nordisk's Wegovy, Ozempic and Rybelsus formulations, or tirzepatide, the active ingredient in Eli Lilly's Zepbound and Mounjaro."

14. KFF Health News republished the CBS News article reporting that 2 million patients obtain their prescription from compounding pharmacies. Exhibit 38 is a true and correct copy of the KFF Health News article.

15. As Chairman of OFA, I am aware of submissions to FDA demonstrating compounding pharmacies filling hundreds of thousands of Tirzepatide prescriptions since October

2024. A true and correct copy of Tenille Davis's December 17, 2024 letter to FDA is attached as Exhibit 39.

16. Specifically, I personally provided FDA with information regarding the Tirzepatide shortage and am aware of agents of OFA providing weekly submissions to FDA of documents providing evidence of Tirzepatide shortage. On September 9, 2024, FDA officials Huascar Batista, Gabrielle Cosel, Valerie Jensen, Kathleen Anderson, and Gail Bormel met with me, Andrew Van Ostrand (Hims & Hers), and Marc Wagner (Baker & Hostetler LLP) to discuss the shortage. On the call, FDA was fully informed about the weekly submissions, was asked for input, and declined to provide feedback or ask questions.ten

17. Examples of submissions to FDA include the following exhibits.

18. A true and correct copy of Hims & Hers GLP-1 accessibility data as of November 3, 2024 is attached as Exhibit 7 and was submitted by OFA to FDA on November 12, 2024.

19. A true and correct copy of Hims & Hers GLP-1 accessibility data as of December 8, 2024 is attached as Exhibit 14 and was submitted by OFA to FDA on December 17, 2024.

20. A true and correct copy of 12.14 Wholesaler Data is attached as Exhibit 15 and was submitted by OFA to FDA on December 17, 2024.

21. A true and correct copy of GLP1_Shortage_Responses_20241020 is attached as Exhibit 18 and was submitted by OFA to FDA on October 29, 2024.

22. A true and correct copy of "Tirzepatide Shortage Reporting Form (10-23-24)_Redacted" is attached as Exhibit 34 and was submitted by OFA to FDA on October 23, 2024.

23. A true and correct copy of "APC_Tirzepatide Is Still in Shortage" is attached as Exhibit 35 and was submitted by OFA to FDA on October 23, 2024.

24. Because many patients fill their prescriptions through compounding pharmacies, the shortages will be exacerbated when patients are no longer able to fill prescriptions from compounding pharmacies.

FDA Was Presented with Evidence of Ongoing Shortage

25. OFA and its agents submitted to FDA on a regular basis substantial documentation evidencing an ongoing shortage of Tirzepatide, including the following exhibits.

26. A true and correct copy of Scott Brunner's October 12, 2024 letter to FDA is attached as Exhibit 3.

27. A true and correct copy of MarketLine's October 22, 2024 article "MangoRx hits back at Eli Lilly's weight loss drug copycat claims" is attached as Exhibit 4, and was submitted by OFA to FDA on November 6, 2024.

28. A true and correct copy of The Plainsman's October 31, 2024 article "The Weight of Weight-Loss Drugs" is attached as Exhibit 5, and was submitted by OFA to FDA on November 6, 2024.

29. A true and correct copy of Cardinal Health's November 1, 2024 earnings call transcript is attached as Exhibit 6, and was submitted by OFA to FDA on November 6, 2024.

30. A true and correct copy of Hims & Hers GLP-1 accessibility data as of November 3, 2024 is attached as Exhibit 7 and was submitted by OFA to FDA on November 12, 2024.

31. A true and correct copy of Dr. Adam Ripley's November 12, 2024 letter to FDA is attached as Exhibit 8.

32. A true and correct copy of KFF Health News's December 2, 2024 article "Who Gets Obesity Drugs Covered by Insurance?" is attached as Exhibit 9 and was submitted by OFA to FDA on December 4, 2024.

33. A true and correct copy of USA Today's December 3, 2024 article "Weight loss drug co-pays skyrocket for some patients" is attached as Exhibit 10 and was submitted by OFA to FDA on December 4, 2024.

34. A true and correct copy of CNBC's December 5, 2024 article "Prescription fill for weight loss drugs Zepbound and Wegovy more than doubled in 2024" is attached as Exhibit 11 and was submitted by OFA to FDA on December 6, 2024.

35. A true and correct copy of NCPA's December 10, 2024 article "Express Scripts Pharmacy no longer taking new GLP-1 customers" is attached as Exhibit 12 and was submitted by OFA to FDA on December 11, 2024.

36. A true and correct copy of CNBC's December 11, 2024 article "Ro to offer lower-price vials of weight loss drug Zepbound by teaming up with Eli Lilly" is attached as Exhibit 13 and was submitted by OFA to FDA on December 13, 2024.

37. A true and correct copy of Hims & Hers GLP-1 accessibility data as of December 8, 2024 is attached as Exhibit 14 and was submitted by OFA to FDA on December 17, 2024.

38. A true and correct copy of 12.14 Wholesaler Data is attached as Exhibit 15 and was submitted by OFA to FDA on December 17, 2024.

39. A true and correct copy of MedPage's December 16, 2024 article "Newer Diabetes Drugs Still Under-Prescribed in High-Risk Patients" is attached as Exhibit 16 and was submitted by OFA to FDA on December 17, 2024.

40. A true and correct copy of Change.org Petition "Protect Patients: Demand the FDA Ensure Access to Affordable GLP-1 Medications!" as of December 18, 2024 is attached as Exhibit 17 and was submitted by OFA to FDA on December 18, 2024.

41. A true and correct copy of GLP1_Shortage_Responses_20241020 is attached as Exhibit 18 and was submitted by OFA to FDA on October 29, 2024.

42. A true and correct copy of "Mounjaro-Zepbound Stock 12.13.2024" is attached as Exhibit 19 and was submitted by OFA to FDA on December 18, 2024.

43. A true and correct copy of "Mounjaro Shortage 12.18" is attached as Exhibit 20 and was submitted by OFA to FDA on December 18, 2024.

44. A true and correct copy of "Mounjaro Shortage 2 12.18" is attached as Exhibit 21 and was submitted by OFA to FDA on December 18, 2024.

45. A true and correct copy of "Mounjaro Shortage 3 12.18" is attached as Exhibit 22 and was submitted by OFA to FDA on December 18, 2024.

46. A true and correct copy of "Mounjaro Shortage 4 12.18" is attached as Exhibit 23 and was submitted by OFA to FDA on December 18, 2024.

47. A true and correct copy of "Zep Mounjaro Shortage 12.18" is attached as Exhibit 24 and was submitted by OFA to FDA on December 18, 2024.

48. A true and correct copy of "Zep Mounjaro Shortage 2 12.18" is attached as Exhibit 25 and was submitted by OFA to FDA on December 18, 2024.

49. A true and correct copy of "Zep Mounjaro Shortage 3 12.18" is attached as Exhibit 26 and was submitted by OFA to FDA on December 18, 2024.

50. A true and correct copy of "Zep Mounjaro Shortage 4 12.18" is attached as Exhibit 27 and was submitted by OFA to FDA on December 18, 2024.

51. A true and correct copy of "Zep Mounjaro Shortage 5 12.18" is attached as Exhibit 28 and was submitted by OFA to FDA on December 18, 2024.

52. A true and correct copy of "Zep Mounjaro Shortage 6 12.18" is attached as Exhibit 29 and was submitted by OFA to FDA on December 18, 2024.

53. A true and correct copy of "Zep Mounjaro Shortage 7 12.18" is attached as Exhibit 30 and was submitted by OFA to FDA on December 18, 2024.

54. A true and correct copy of "Zep Shortage 2 12.18" is attached as Exhibit 31 and was submitted by OFA to FDA on December 18, 2024.

55. A true and correct copy of "Zep Shortage 3 12.18" is attached as Exhibit 32 and was submitted by OFA to FDA on December 18, 2024.

56. A true and correct copy of "Zep Shortage 4 12.18" is attached as Exhibit 33 and was submitted by OFA to FDA on December 18, 2024.

57. A true and correct copy of "Tirzepatide Shortage Reporting Form (10-23-24)_Redacted" is attached as Exhibit 34 and was submitted by OFA to FDA on October 23, 2024.

58. A true and correct copy of "APC_Tirzepatide Is Still in Shortage" is attached as Exhibit 35 and was submitted by OFA to FDA on October 23, 2024.

Shortages Persist Despite Access to Compounded Tirzepatide

59. From news sources to trade publications to online forums, there has been widespread reporting on patients' continued inability to fill prescriptions for Tirzepatide, despite assertions from the drug manufacturers about availability. *See, e.g.*, Exs. 3-40. My conversations and correspondence with OFA members confirm that these reports are accurate: even with compounded forms of Tirzepatide available, market demand has not been satisfied since.

60. Because the market demand for Tirzepatide has been exceptionally high, patients have turned to compounding pharmacies to fill prescription orders that could not be filled

otherwise. Even with compounding pharmacies and outsourcing facilities providing millions of Tirzepatide doses per month, patients around the country have still struggled to get their prescriptions timely filled. *See* Ex. 40. Some patients have been forced to wait days or weeks to have their Tirzepatide prescriptions filled.

61. Demand for compounded Tirzepatide has remained at exceptionally high levels through the month of January 2025, including right up to the time of the FDA's announcement that Tirzepatide is no longer in shortage. *See* Ex. 40.

FDA Knew the Shortage Persisted Yet Delisted Tirzepatide Without Notice and Comment

62. Various industry participants have recently and consistently presented FDA information showing extremely high demand for Tirzepatide, inability of its manufacturer to keep up, scarcity in various regions and at the national level, and delays in filling prescriptions. *See, e.g.*, Exs. 7, 14, 15, 17-35, 40.

63. I have personal knowledge of specific submissions of information directly to FDA showing that a shortage for Tirzepatide exists: this information must be included on any fairly compiled administrative record in this case. I am aware that FDA received information from at least two major national telehealth companies, which collect information from customers about ability to obtain drugs. One reported to FDA on September 10, 2024, that it received 500 to 700 *daily* reports of patients reporting to *just that company* an inability to obtain a branded version of Tirzepatide. Another sent FDA periodic updates to FDA, including thousands of shortage reports indicating inability of patients to obtain Mounjaro and Zepbound.

64. FDA also received reports from outsourcing pharmacies (including OFA members) of voluminous Tirzepatide compounding meeting high demand. I personally reported to FDA that

OFA members were seeing very high demand that the supply side of the market—even with drug compounding—was not adequately meeting.

65. Despite the evidence, FDA declared on December 19, 2024 that the Tirzepatide shortage was resolved and removed Tirzepatide from the shortage list.

66. FDA did not undertake notice-and-comment rulemaking before declaring the shortage over.

FDA's Delisting Action Causes Severe Harm to OFA and Its Members

67. Because FDA removed Tirzepatide from the shortage list, and because Tirzepatide is not on the clinical need list, bulk compounding of Tirzepatide will become categorically unavailable under Section 503B and thus will be prohibited to all OFA's members and all FDA-registered 503B outsourcing facilities.

68. As noted above, all OFA's members are outsourcing facilities or are affiliated with outsourcing facilities that operate under Section 503B. Because a shortage listing is a necessary prerequisite to compounding under Section 503B if a bulk drug substance is not listed on the 503B Bulks List, Tirzepatide is not listed on the 503B Bulks List, FDA's action will categorically bar every OFA member from compounding Tirzepatide.

69. FDA's delisting decision will close off an important source of market supply that met a sweeping scope of demand up until the decision. OFA members have produced millions of doses of compounded Tirzepatide from June 1 2024, through November 30, 2024, which moved promptly from their storage to pharmacies and other lawful purchasers, reflecting continued high demand and short supply.

70. OFA members are aware of thousands of unique customers in recent weeks unable to access branded forms of Tirzepatide. *See* Ex. 40. There is every reason to believe that cutting

off supply through compounding will leave patient needs unfilled on a large scale, which will in turn exacerbate the public-health crises of obesity and diabetes. OFA is continuing to receive information of shortages, including from patients and consumers unable to obtain Tirzepatide products.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on the 28th day of January, 2025.

/s/ Lee Rosebush
Lee Rosebush

Exhibit 1

U.S. FOOD & DRUG ADMINISTRATION

Date: December 19, 2024

From: CDR Robert Kosko
Consultant
CDER Drug Shortage Staff

Through: Valerie Jensen, R.Ph.
Associate Director
CDER Drug Shortages Staff

Valerie E. Jensen -S

Digitally signed by Valerie E. Jensen -S
Date: 2024.12.19 07:00:41 -05'00'

To: CDER Drug Shortage File

Subject: Resolution of Tirzepatide Injection Product Shortage and Supply Status

Tirzepatide injection products were first added to FDA's drug shortage list on December 15, 2022. The Agency determined that the shortage was resolved and removed tirzepatide injection products from FDA's drug shortage list on October 2, 2024.[1] FDA has now reevaluated that decision.[2] For the reasons below, FDA has determined upon reevaluation that the tirzepatide injection product shortage is resolved.

FDA is instructed to "maintain an up-to-date list of drugs that are determined by [FDA] to be in shortage in the United States,"[3] and a "shortage" is "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug."[4] Eli Lilly and Company ("Lilly"), the manufacturer of the relevant tirzepatide injection drug products, has provided FDA with detailed information and data regarding its production and inventory of these drug products at various points in time, including stock reports that show quantities supplied and demanded, and inventory held in stock, for all strengths of these drug products; cumulative quantities supplied to and demanded by its customers in the year 2024; projected demand and supply in future months; and wholesaler inventory data, among other information. (See Section II.A.). We conclude that the information and data Lilly has provided to FDA demonstrate that Lilly's supply is currently meeting or exceeding demand for these drug products, and that Lilly has developed reserves that it now holds in its finished product inventory, plus significant units of semi-finished product, and has scheduled substantial additional production over the coming months, such that supply will meet or exceed projected demand.

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[1] https://dps.fda.gov/drugshortages/resolved/tirzepatide-injection.

[2] On October 7, 2024, FDA was sued in the U.S. District Court for the Northern District of Texas by the Outsourcing Facilities Association and North American Custom Laboratories, LLC d/b/a Farmakeio Custom Compounding regarding removal of tirzepatide injection from FDA's drug shortages list. On October 11, 2024, upon FDA's motion, a court order remanded the decision to the Agency for reevaluation. *See Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-953, ECF Nos. 27, 28 (N.D. Tex.).

[3] Section 506E(a) of the FD&C Act.

[4] Section 506C(h)(2) of the FD&C Act; 21 CFR 314.81(b)(3)(iii)(f).

U.S. Food & Drug Administration
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Silver Spring, MD 20993
www.fda.gov

FDA has also considered potentially relevant information regarding the shortage determination from patients, healthcare providers, and others, including compounders, along with data from other sources that we independently identified. (See Section II.B.). After carefully evaluating this information, we find that it has important limitations. We conclude that this information does not undermine or outweigh the evidence demonstrating that Lilly's supply is currently meeting or exceeding demand and that, based on our best judgment, it will meet or exceed projected demand.

For example, FDA received reports that some patients and pharmacists are not able to obtain the approved drugs, and that a substantial amount of tirzepatide compounding is occurring. The information provided in Lilly's submissions demonstrate that the company is currently meeting or exceeding demand for Mounjaro and Zepbound. That is not inconsistent with some, and even many, individuals having had some trouble getting prescriptions for the affected drugs filled over the course of the shortage, and some individuals may still be currently encountering such challenges, even though Lilly's supply is now meeting or exceeding demand nationally. In our assessment, intermittent challenges of this kind are most likely explained not by a continuing national shortage of supply, but by the practical dynamics of the portion of the supply chain between Lilly and the individual customers, including wholesale distributors and retailers. We recognize that significant compounding of tirzepatide injection products is occurring, and that some number of patients currently receiving those products can be expected to seek Lilly's approved products at a future point when compounding is curtailed. However, the additional information provided by patients, healthcare providers, and others, including compounders does not demonstrate that Lilly will be unable to meet projected demand, especially when weighed against the Lilly-provided data.

For all of these reasons and as explained further below, we determine that the shortage is resolved. Our determination is based on our conclusions that supply meets or exceeds current demand, and that, based on our best judgment looking at the available information with its limitations, supply will also meet or exceed projected demand.

FDA will continue to monitor supply and demand for these products, and whether any tirzepatide injection products should be included on the drug shortage list in the future, as appropriate.[5]

This memo also explains that, in addition to the representations FDA made regarding enforcement in October 2024 in connection with litigation,[6] FDA does not intend to take action against compounders for violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act) arising from conditions that depend on tirzepatide injection products' inclusion on the FDA drug shortage list (see section 506E of the FD&C Act) [i.e., section 503A(b)(1)(D) (compounded drugs that are essentially a copy of a commercially available drug product) or sections

[5] Notwithstanding resolution of the shortage, FDA understands that patients and prescribers may still see intermittent localized supply disruptions as the products move through the supply chain from the manufacturer to wholesale distributors and pharmacies.

[6] *See* Defendants' Unopposed Motion for Voluntary Remand and Stay, *Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-953, ECF No. 27, at 3. *See also* Letter from Gail Bormel, Office Director, CDER Office of Compounding Quality and Compliance, to Scott Brunner, Chief Executive Officer, Alliance for Pharmacy Compounding (APC) (Oct. 17, 2024), available at https://www.fda.gov/media/182948/download?attachment.

503B(a)(2)(A) (bulk drug substances used in compounding) and (a)(5) (compounded drugs that are essentially a copy of an FDA-approved drug product)] for the following time periods from the date of this memorandum:

- For state-licensed pharmacists or physicians compounding under section 503A of the FD&C Act, 60 calendar days from the date of this memorandum, until February 18, 2025; and
- For outsourcing facilities under section 503B of the FD&C Act, 90 calendar days from the date of this memorandum, until March 19, 2025.

I. Background

FDA maintains an up-to-date list of drugs that are determined by the Agency to be in shortage in the United States.[7] FDA's drug shortage list is publicly available on the Agency's website.[8] FDA's drug shortage list includes the names and National Drug Code (NDC) numbers for such drugs; the name of each applicant for such drugs, the reason for the shortage as determined by FDA, and the estimated duration of the shortage.[9]

In this context, a drug shortage means "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug."[10] As such, in determining whether a drug is in shortage for purposes of the FD&C Act, FDA evaluates the supply and demand or projected demand of the drug on a nationwide level, across the entire market, not at the local level.[11] The Agency acknowledges that even when a shortage is considered resolved, patients and prescribers may still see intermittent localized supply disruptions as products move through the supply chain from the manufacturer and distributors to local pharmacies.

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[7] See section 506E(a) of the FD&C Act (21 U.S.C. 356e) and 21 CFR 314.81(b)(3)(iii)(*d*)(*1*). Manufacturers of certain prescription drug products must notify FDA of a permanent discontinuance in the manufacture of the drug product, or an interruption in manufacturing of the drug product that is likely to lead to a meaningful disruption in supply of that drug in the United States, and the reasons for such discontinuance or interruption. For the same drugs, manufacturers are also required to report a permanent discontinuance in the manufacture of an active pharmaceutical ingredient of the drug or an interruption in the manufacture of an active pharmaceutical ingredient likely to lead to a meaningful disruption in supply of the manufacturer's drug, and the reasons for the discontinuance or interruption. See section 506C of the FD&C Act and 21 CFR 314.81(b)(3)(iii).

[8] https://dps.fda.gov/drugshortages. See section 506E(c) of the FD&C Act and 21 CFR 314.81(b)(3)(iii)(*d*)(*1*).

[9] See section 506E(b) of the FD&C Act and 21 CFR 314.81(b)(3)(iii)(*d*)(*1*). FDA cannot disclose trade secret or commercial or financial information that is considered confidential or privileged. See sections 506C(d) and 506E(c)(2) of the FD&C Act and 21 CFR 314.81(b)(3)(iii)(*d*)(*2*). Additionally, FDA may choose not to make drug shortage information publicly available if FDA determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of drug products to patients). See section 506E(c)(3) of the FD&C Act and 21 CFR 314.81(b)(3)(iii)(*d*)(*2*).

[10] Section 506C(h)(2) (21 U.S.C. 356c) of the FD&C Act; see also 21 CFR 314.81(b)(3)(iii)(*f*).

[11] See FDA Strategic Plan for Preventing and Mitigating Drug Shortages (October 2013), available at https://www.fda.gov/media/86907/download. See also CDER's manual of policies and procedures on drug shortage management (MAPP 4190.1 Rev. 4), available at https://www.fda.gov/media/72447/download; and FDA's draft guidance for industry, *Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Products or Active Pharmaceutical Ingredients Under Section 506C of the FD&C Act* (February 2024), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-discontinuance-or-interruption-manufacturing-finished-products-or-active. This draft guidance, when finalized, will represent FDA's current thinking on this topic.

FDA receives input regarding drug shortages from numerous stakeholders, including manufacturers, patients, healthcare providers, and others, including compounders.[12] In particular, manufacturers are required to notify FDA about discontinuances and manufacturing interruptions pertaining to certain drugs pursuant to statutory and regulatory requirements,[13] and they may voluntarily provide additional information as relevant about quality issues, increases in demand, recalls, or other events (e.g., relevant supply and demand conditions).

Tirzepatide is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist. Mounjaro and Zepbound are the only FDA-approved tirzepatide products. Mounjaro (tirzepatide) injection, for subcutaneous use, is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Mounjaro is approved as pre-filled single-dose pens in several strengths (2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5 mg/0.5 mL, 10 mg/0.5 mL, 12.5 mg/0.5 mL, and 15 mg/0.5 mL). The Mounjaro pen products were approved by FDA in May 2022 (NDA 215866) and added to FDA's drug shortage list in December 2022 due to high demand. Mounjaro single-dose vial products in the same strengths were approved in a supplement to NDA 215866 in July 2023, but are not currently marketed in the United States and have not been on FDA's drug shortage list. Zepbound (tirzepatide) injection, for subcutaneous use, is indicated in combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition. Zepbound is also approved as pre-filled single-dose pens and single-dose vials in the same strengths as Mounjaro (2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5 mg/0.5 mL, 10 mg/0.5 mL, 12.5 mg/0.5 mL, and 15 mg/0.5 mL). The Zepbound pen products were approved by FDA in November 2023 (NDA 217806) and added to FDA's drug shortage list in April 2024 due to high demand. The Zepbound single-dose vial products were approved in a supplement to NDA 217806 in March 2024, but only the 2.5 mg and 5.0 mg strengths are currently being marketed in the United States. The Zepbound vial products have never been on the shortage list.[14]

II. Discussion

A. Manufacturer-provided information about availability

Since August 2, 2024, Lilly has stated that it is able to meet or exceed demand for all strengths of Mounjaro (tirzepatide) injection and Zepbound (tirzepatide) injection in the United States.[15] Since (b) (4), Lilly has been providing FDA with supply and demand data on its tirzepatide injection products to support its assertion that no strengths of Mounjaro or Zepbound

[12] FDA's website includes information about drug shortage notifications for industry and a public portal for patients, healthcare providers, and organizations to report new shortages, available at https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages.

[13] Section 506C(h)(2) of the FD&C Act; 21 CFR 314.81(b)(3)(iii)(f).

[14] (b) (4)

[15] See (b) (4), (b) (6)

are in shortage (b) (4).[16] These data included stock reports, cumulative supply and demand reports, and distributor inventory reports. In addition, Lilly has responded to multiple FDA requests for information regarding these data. We have reviewed Lilly's submissions and find that they support the conclusion that supply is currently exceeding demand and will meet or exceed projected demand across all strengths of Mounjaro and Zepbound.

1. Lilly's Data Demonstrate that Its Supply is Currently Meeting Demand

Inventory Data. (b) (4), Lilly has been providing "stock reports," which contain data on its inventory and orders for its Mounjaro and Zepbound products, by dosage strength.[17] These data demonstrate that Lilly has been filling wholesale orders as they are received while generally maintaining product in inventory net of open orders (i.e., allocating sufficient product to fulfill all existing orders before counting any product on hand as excess inventory). See Table 1 below for net inventory balances for each Mounjaro and Zepbound single-dose pens, by strength. (b) (4)

[16] (b) (4), (b) (6) Lilly first provided these data for tirzepatide generally, and later disaggregated the data between Mounjaro and Zepbound.

[17] (b) (4)

[18] Id.

(b) (4), Lilly had all strengths of Mounjaro and Zepbound in stock, net of open orders.[19]

Importantly, Lilly stated that it does not — and has not — limited the ability of any wholesaler to place orders for any quantities of Mounjaro or Zepbound.[20] (b) (4) Lilly states that (b) (4) [21] Lilly explained that (b) (4) [22]

Lilly's stock reports also provided FDA with information about the amount of "semi-finished units" (i.e., products that have already completed sterile manufacturing and are awaiting labeling and packaging) in its supply over time. Lilly explained that (b) (4)

Lilly has stated that it has a reserve supply (i.e., finished goods inventory in its warehouse) that supports maintaining (b) (4) depending on dose level demand, net of open orders.[24]

We find that the stock reports demonstrate that Lilly has been filling wholesale orders as they are received while maintaining product in inventory net of open orders. Significant units of semi-finished product also provide assurance that Lilly will continue to be able to fill orders as they are received. Therefore, these reports support our conclusion that supply is meeting or exceeding demand for these drugs.

[19] (b) (4)
[20] Id. at 7.
[21] Id.
[22] Id.
[23] Id. at 3.
[24] (b) (4)

Table 1. Net Inventory Balance and Doses of Semi-finished Syringe Product, by Dosage Strength (in thousands)[25]

	Product	Net Inventory Balance at Lilly, finished product (thousands of doses)*	Units of TZP Semi-finished Syringe Product at Lilly (thousands of doses)*
2.5 mg	MJO	(b) (4)	
	ZEP		
5 mg	MJO		
	ZEP		
7.5 mg	MJO		
	ZEP		
10 mg	MJO		
	ZEP		
12.5 mg	MJO		
	ZEP		
15 mg	MJO		
	ZEP		
TOTAL			

***** Lilly inventory reflects domestic inventory only and does not include (b) (4)

****** (b) (4)

Cumulative Supply and Demand Data. In addition to the stock reports, Lilly provided historic data on monthly cumulative supply and demand of the single-dose pens, by strength, of Mounjaro and Zepbound, since January 2024. The supply figures represent (b) (4) These data demonstrate that the company's supply has met or exceeded demand throughout 2024, with increasing amount of additional supply over the course of the year. In total, the company reported that it has supplied more than (b) (4) of tirzepatide injections since the beginning of 2024, significantly exceeding overall demand of around (b) (4).[28] Furthermore, cumulative supply for Mounjaro and Zepbound, in all strengths, has exceeded demand in this period. See Table 2 below for Lilly-reported demand and supply of Mounjaro, (b) (4), by strength. See Table 3 below for Lilly-reported demand and supply of

[25] (b) (4)

[26] (b) (4)

[27] Id. at 6.

[28] (b) (4)

Zepbound, (b) (4), by strength. Although Lilly did not provide cumulative supply and demand data broken down by product (b) (4) in its most recent submission (b) (4), we received aggregated data (b) (4) which shows the same trend – cumulative supply is continuing to outpace demand. See Table 4 below for Lilly-reported demand and supply of tirzepatide single-dose pens (b) (4) by strength. Therefore, the cumulative demand and supply data further support our conclusion that supply is meeting or exceeding demand for these drugs.

Table 2. Lilly-reported cumulative demand and cumulative supply of Mounjaro single-dose pens (thousands of doses)[29]

Cum. demand	(b) (4)
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Cum. supply	
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Net (cum. supply – cum. demand)	
2.5	
5	
7.5	
10	
12.5	
15	
Total	

[29] Id.

Table 3. Lilly-reported cumulative demand and cumulative supply of Zepbound single-dose pens (thousands of doses)[30]

Cum. demand	(b) (4)
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Cum. supply	
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Net (cum. supply – cum. demand)	
2.5	
5	
7.5	
10	
12.5	
15	
Total	

[30] Id. The table provides data only for pre-filled Zepbound pens and does not include vials.

Table 4. Lilly-reported cumulative demand and cumulative supply of tirzepatide single-dose pens (b) (4) (thousands of doses)[31]

Cum. demand	(b) (4)
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Cum. supply	
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Net (cum. supply – cum. demand)	
2.5	
5	
7.5	
10	
12.5	
15	
Total	

Lastly, we note that since August 2024, Lilly has also been selling vial forms of Zepbound (2.5mg and 5.0mg) directly to patients with prescriptions through "LillyDirect." Additionally, in December 2024, Lilly reportedly reached an agreement to market Zepbound vials through the telehealth platform Ro.[32] These vial products have never been listed as being in shortage, and Lilly has reported that, since marketing, their cumulative supply has exceeded cumulative demand. For example, Lilly reported that, (b) (4)

[31] (b) (4)

[32] Elaine Chen and Katie Palmer, "Eli Lilly strikes Zepbound deal with Ro, amid questions about future of compounded GLP-1s," STAT+ Pharma, Dec. 11, 2024, available at https://www.statnews.com/2024/12/11/eli-lilly-zepbound-ro-health-agreement-weight-loss/.

[33] (b) (4)

[34] Id.

1. Significant Inventory is Present Elsewhere in the Distribution Channel

In addition to the net inventory and semi-finished product held by Lilly discussed above, there is additional product in the distribution channel, i.e., the part of the supply chain between Lilly and individual patients, including wholesale distributors and retail pharmacies. Lilly explained that

(b) (4)

[redacted]

[35] (b) (4)

[36] Id. at 5.

[37] Id. at 7. (b) (4)

[redacted]

Id.

[38] Id. at 4.

Table 5. Lilly Reported Volume of Mounjaro and Zepbound Pre-Filled Pens Shipped to Wholesalers and Average Wholesaler Daily Inventory (in units, with each unit containing 4 doses)[39]

(b) (4)	Volume Shipped (Units)	Avg. Daily Inventory (Units)
Mounjaro		
2.5	(b) (4)	
5		
7.5		
10		
12.5		
15		
Total		
Zepbound		
2.5		
5		
7.5		
10		
12.5		
15		
Total		
Total Mounjaro + Zepbound		

Adequate supply at the wholesaler level is further supported by the fact that, (b) (4) further indicate that nationwide supply for its products is exceeding demand.

[39] Id. at 5. The table provides data only for pre-filled Mounjaro and Zepbound pens and does not include vials.
[40] (b) (4)
[41] (b) (4)
[42] (b) (4)
[43] Id.

In sum, data relating to wholesaler inventory support our conclusion that supply is meeting or exceeding demand for these drugs.[44]

2. Supply is Forecasted to Exceed Projected Demand

As explained above, the FD&C Act defines a drug shortage as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug."[45] As such, we must also consider whether supply will meet or exceed projected demand for these drugs. In its (b) (4), Lilly represented that it is "positioned to supply more than projected demand and without any large-scale nationwide disruptions."[46] Lilly went on to state that it is "now able to supply (b) (4) per month," and "[i]n just the first two months of Q4 2024, Lilly has already supplied (b) (4) of Mounjaro and Zepbound and expects to supply (b) (4) by the end of the quarter."[47]

Lilly explained that (b) (4)

[44] (b) (4)

[45] Section 506C(h)(2) of the FD&C Act; see also 21 CFR 314.81(b)(3)(iii)(*f*).

[46] (b) (4)

[47] Id.

[48] (b) (4)

[49] Id. at 7.

[50] Id. at 10.

[51] Id. at 7.

[52] Id.

[53] (b) (4)

With respect to compounding, Lilly explained that [redacted] For purposes of this analysis, we believe that approach was reasonable in light of the lack of reliable data from compounders, and the uncertainties in predicting future patient and prescriber behavior, for the reasons explained below (see section II.B.2 below). While we acknowledge the possibility that growth in demand for Lilly's products may exceed its current demand projections as a result of compounding being curtailed in the future, the information available to us does not support a conclusion that such growth in demand will exceed Lilly's supply.

Lilly explained that, based on its forecast, it [redacted] We

[redacted]

54 [redacted]

55 Id.

56 [redacted]

57 [redacted]

agree that Lilly has reasonably assessed projected supply and demand, (b) (4) gives us further confidence in the accuracy of Lilly's predictions of future demand. Based on this information, we conclude that based on our best judgment, supply will meet or exceed projected demand.

Table 6. Lilly-reported projected cumulative demand and cumulative supply of tirzepatide single-dose pens, (b) (4) (thousands of doses)[58]

Cum. demand	(b) (4)
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Cum. supply	
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Net (cum. supply – cum. demand)	
2.5	
5	
7.5	
10	
12.5	
15	
Total	

Lastly, we also note that with respect to the Zepbound vial products that have not been listed as being in shortage, Lilly has reported that (b) (4)

Taken as a whole, the data and information submitted by Lilly support our conclusion that supply is currently meeting or exceeding demand and, based on our best judgment looking at the available information with its limitations, will meet or exceed projected demand across all strengths of Mounjaro and Zepbound.[60]

58 (b) (4)

59 (b) (4)

60 (b) (4)

B. Other information about availability

FDA also has received and considered other information potentially related to supply and demand for tirzepatide injection products in the United States. This information can be generally categorized as (1) information from sources other than Lilly bearing on *current* supply and demand, (2) information about compounded drug products bearing on *projected* demand, and (3) other information. After careful consideration, this information does not alter our conclusions that supply is meeting or exceeding demand and, based on our best judgment looking at the available information with its limitations, will meet or exceed projected demand, and thus that the shortage is resolved.

1. Information from Sources Other Than Lilly Regarding Current Supply and Demand

FDA received submissions from multiple sources other than Lilly, including telehealth companies, pharmacy compounders, associations representing pharmacy compounders and outsourcing facilities, and individuals. Some stakeholders characterized their submissions as providing "evidence of extremely high demand for Tirzepatide, scarcity in various regions and at the national level, and delays in filling prescriptions" and "information demonstrating that supply continued to lag behind demand, even at stark levels."[61] The submitted information generally falls into the following categories, each of which is discussed in turn below.

- Information collected from individual customers reporting "inability of patients to obtain Mounjaro and Zepbound;"[62]
- Information regarding the ability of retail pharmacies to obtain Mounjaro and Zepbound from wholesalers;
- Articles reported in the press and published on industry websites;[63]
- Individual comments on FDA's general compounding docket, FDA-2015-N-0030; and
- Reports of "voluminous Tirzepatide compounding meeting high demand."[64]

i. Information collected from individual patients reporting "inability of patients to obtain Mounjaro and Zepbound."

FDA received multiple submissions stating that individual patients are unable to access Mounjaro or Zepbound, which the submitters urge FDA to consider as evidence that a shortage persists. FDA considered this information, and concludes that it does not undermine or outweigh the information submitted by Lilly, described above, which demonstrates that supply of

[61] Complaint, *Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-00953-P (E.D. Tex. filed Oct. 7, 2024), Dkt. 1, at 9, ¶ 29. *See also id*. at 17, ¶ 69 (characterizing evidence as showing "continued inability of supply to keep pace with demand").
[62] Id.
[63] Id.
[64] Plaintiffs' Memorandum of Law in Support of a Temporary Restraining Order and Preliminary Injunction, *Outsourcing Facilities Ass'n*, No. 4:24-cv-00953-P, Dkt. 8, at 17 (Oct. 8, 2024); *id*. Dkt. 9 (Appendix in Support of Plaintiffs' Mot.).

Mounjaro and Zepbound is currently meeting demand. Below we discuss two examples of such submissions in detail.

As one example, Hims & Hers Health, Inc. submitted multiple reports to FDA that it characterized as demonstrating that "the shortage persists."[65] These reports include data regarding the number of people that have reported to Hims & Hers "an inability to access name brand GLP-1s," including Mounjaro and Zepbound, reported weekly and cumulatively.[66] Plaintiffs in *Outsourcing Facilities Ass'n v. FDA* characterized these reports as "survey data . . . show[ing] increasing numbers of patients unable to obtain branded GLP-1 agonist products, including specifically branded Tirzepatide products."[67] These reports appear to be generated by collecting data through the Hims & Hers website, using an internet form that anyone can complete.[68] The company describes the data it is collecting as "helping Hims & Hers keep the FDA updated on GLP-1 shortages across the country . . . This tracker allows people to share their experiences and keep the FDA updated with the latest supply information."[69] Hims & Hers further states that the tracker can be used by "[a]nyone who has had trouble getting access to a GLP-1 medication in the past," and that the way to "report a weight loss drug shortage to the FDA" is to "[s]hare your current state of residence, the GLP-1 medication, and the dosage you've had trouble accessing in the past."[70] No further limitations (such as by date, restricting reporting to recent access challenges) or instructions (such as defining "trouble accessing" a drug) are provided for those filling out the form, nor does the form collect any details regarding their location or experiences.[71]

As another example, the Outsourcing Facilities Association (OFA) submitted "time-stamped reports of drug shortages for FDA-approved tirzepatide that the OFA has received from patients."[72] The submitted list included, for around 100 entries, a date and time (presumably the date and time of the communication from the patient to OFA), patient zip code, and a yes/no answer to the question "Have you attempted to have a prescription filled at more than one pharmacy?" (most but not all of which are answered "Yes").[73] It is not clear how this

[65] Dec. 2, 2024 email from Andrew Van Ostrand, Vice President, Policy & Regulatory Affairs, Hims & Hers Health, Inc. to Valerie Jensen and Gail Bormel, FDA, "updated Hims & Hers Health, Inc. GLP-1 access/shortage data – the shortage persists," with attachments.
[66] *Id.* at attachment 1 and 2. See also Dec. 16, 2024 email from Andrew Van Ostrand to Valerie Jensen and Gail Bormel, "Hims & Hers Health, Inc. GLP-1 shortage data - as of 12/14/24," with attachment.
[67] Joint Status Report, *Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-00953-P, Dkt. 30, at 1-2 (N.D. Tex., Nov. 21, 2024).
[68] See https://investors.hims.com/news/news-details/2024/Americans-Continue-to-Struggle-to-Access-Branded-GLP-1s-as-Shortages-Continue/default.aspx (describing "tracker").
[69] https://www.hims.com/weight-loss/supply-tracker (internet form 1) ("Frequently asked questions"); and https://www.forhers.com/weight-loss/supply-tracker (internet form 2) ("Frequently asked questions").
[70] Id.
[71] Id.
[72] Oct. 23, 2024 email from Marc Wagner, counsel for OFA, to Valerie Jensen and CDER DRUG SHORTAGES, FDA, "Patient reported shortages of FDA-approved tirzepatide," with attachments.
[73] Id. at attachment 1.

information was collected, and, like the information submitted by Hims & Hers, it does not include details of the reported individual experiences.

This information does not undermine or outweigh the information provided by Lilly, discussed in section II.A above, with respect to availability of its products. As discussed in greater detail above, the information and data provided in Lilly's submissions demonstrate that the company is currently meeting or exceeding demand for Mounjaro and Zepbound. That is not inconsistent with some, and even many, individuals having had some trouble getting prescriptions for the affected drugs filled over the course of the shortage, and some individuals may still be currently encountering such challenges, even though Lilly's supply is now meeting or exceeding demand nationally. In our assessment, continuing challenges of this kind are most likely explained not by a continuing national shortage of supply, but by the practical dynamics of the portion of the supply chain between Lilly and the individual customers, including wholesale distributors and retailers. Lilly explained that "[e]ven when a medication is available, patients may not always be able to immediately fill their prescription at a particular pharmacy. That is especially true for refrigerated products and products with multiple dose strengths, due to factors like ordering practices and incentives, cold chain logistical considerations, and retailer capacity constraints. Patients may experience variability at a particular pharmacy location regardless of whether a drug is in shortage."[74] The company further explained that "not every pharmacy has sufficient refrigerator space to store sufficient stock of 12 doses across two brands of approved tirzepatide. (b) (4) and that (b) (4) [75] Also see the discussion in section II.B.1.ii below (regarding wholesaler operations issues that do not necessarily indicate nationwide shortage). In sum, the fact that some pharmacies do not have ample stock of these tirzepatide products on hand at certain points in time does not undermine Lilly's data supporting a conclusion that supply is meeting or exceeding demand.

Further, to the extent that individual challenges in filling prescriptions may bear on factors relevant to the required statutory analysis of supply and demand, the information FDA has received from these stakeholders is inadequate because of the limitations described above. The submitted information does not include details of the reported experiences, and accordingly is not interpretable as to what kind of challenges the individuals actually experienced. For example, one individual might be reporting a pharmacy telling the individual that the prescribed drug was not in stock. On the other hand, another individual might be reporting an inability to get a prescription from a doctor based on the doctor's medical judgment, or an inability to get insurance coverage for a prescribed drug based on the insurance company's policies, and neither situation is relevant to the questions of supply and demand that the statute tasks FDA with analyzing to determine whether a drug shortage exists,[76] but both are better understood as preventing individuals from becoming part of the demand for the drug. Further, the Hims & Hers

74 (b) (4)

75 (b) (4)

76 The statute defines "drug shortage" as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." Section 506C(h)(2) (21 U.S.C. 356c) of the FD&C Act; see also 21 CFR 314.81(b)(3)(iii)(*f*).

internet form used to collect data (an approach that may have been used by some or all of the other data collectors, as well) significantly limits its probative value. Individuals completing the form might not be representative of the U.S. patient population and the data is subject to bias. Because there appears to be no limit on who can fill out the Hims & Hers internet form, it is possible, and perhaps even likely given the context (*see* section II.B.1.iv below, discussing comments received as a product of an internet letter-writing campaign) that some individuals have completed it multiple times. Hims & Hers did not provide information to FDA regarding any controls they may have established to ensure the integrity of the data.[77] Nor did OFA regarding its similar data collection.[78]

Accordingly, these reports do not undermine or outweigh the comprehensive information provided by Lilly regarding supply and demand discussed in section II.A above. That evidence provides a detailed quantitative picture of the supply and demand situation both over time, and at the national level, and is therefore much more probative to the analysis FDA must conduct to determine the status of the shortage.

ii. Information regarding the ability of retail pharmacies to source Mounjaro and Zepbound from wholesalers

Hims & Hers also submitted to FDA certain screenshots that the company asserts demonstrate that "our affiliated pharmacies continue to struggle to source branded GLP-1s across our leading wholesale partners."[79] As relevant to tirzepatide, the most recent report contains a screenshot that appears to show a wholesaler's website listing Mounjaro 5 mg and 10 mg strengths as unavailable, as indicated by text that says "Notify me when this item is in stock."[80] While Hims & Hers indicates that the screenshot represents "Supplier data as of 12/02/2024," the screenshot itself is undated and does not include information about the length of time that the product is or was out of stock.[81] Earlier reports include a similarly limited selection of screenshots purporting to show wholesaler ordering websites with Mounjaro or Zepbound out of stock, such as the November 12, 2024 report, which includes one undated screenshot showing Zepbound 15 mg as "Notify me when this item is in stock," on a wholesaler website.[82]

Similarly, the Alliance for Pharmacy Compounding (APC) gathered similar screenshots on its website, https://a4pc.org/stillinshortage.[83] APC submitted an updated set of screenshots to FDA on December 17, 2024.[84] Like the Hims & Hers screenshots, many of the APC screenshots are

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[77] Dec. 2, 2024 email from Andrew Van Ostrand, Vice President, Policy & Regulatory Affairs, Hims & Hers Health, Inc. to Valerie Jensen and Gail Bormel, FDA, "updated Hims & Hers Health, Inc. GLP-1 access/shortage data – the shortage persists."
[78] Oct. 23, 2024 email from Marc Wagner, counsel for OFA, to Valerie Jensen and CDER DRUG SHORTAGES, FDA, "Patient reported shortages of FDA-approved tirzepatide," with attachments.
[79] Id. at attachment 1, page 4.
[80] Id.
[81] Id.
[82] Nov. 12, 2024 email from sfaltin@forhims.com to CDER DRUG SHORTAGES, "Hims & Hers Health, Week of Oct 6 2024, Weekly GLP-1 shortage data" with attachments, at attachment 1, page 4.
[83] The Outsourcing Facilities Association submitted an email to FDA directing the agency to the APC website, and attaching a screenshot. *See* Oct. 23, 2024 email from Marc Wagner, counsel for OFA, to Valerie Jensen and CDER DRUG SHORTAGES, FDA, "Patient reported shortages of FDA-approved tirzepatide," with attachments.
[84] December 17, 2024 letter from Tenille Davis to Robert Califf, Valerie Jensen, and Gail Bormel, with attachments.

undated.[85] Others, however, do contain date information, including "Updated as of," "Product issue(s) tracked since" and "Expected availability in DC [distribution center]."[86] Plaintiffs in *Outsourcing Facilities Ass'n v. FDA* characterized this evidence as showing that "[p]harmacy distributors continue to list branded Tirzepatide products as out-of-stock or available in only limited quantities."[87]

In addition, FDA received a letter dated October 2, 2024, from a law firm representing "numerous pharmacies," expressing concern that, at that time, they were "continu[ing] to experience significant difficulties in obtaining" tirzepatide.[88] The email stated that "none of the clients can purchase tirzepatide from either McKesson, Bergen, or Cardinal [wholesalers] as all of the local DCs [distribution centers] either have zero in stock or are allocating the pharmacies to 1-2 boxes per day."[89] The letter also stated that "one of our clients reported receiving over 400 prescriptions for tirzepatide but is restricted to purchasing only 2 boxes of drug product due to their wholesaler's purchasing policy."[90]

Similarly, on November 15, 2024, FarmaKeio submitted a comment to FDA's general compounding docket including similar screenshots.[91] The screenshots show multiple strengths of Mounjaro and Zepbound listed as "out of stock" and/or "restricted" in the number a retailer may purchase from wholesalers AmerisourceBergen and Anda on that date.[92]

Upon thorough review, none of this information undermines or outweighs the information provided by Lilly, discussed in section II.A above, with respect to availability of product to wholesalers and retailers. As discussed in greater detail above, Lilly's submission demonstrates that the company is currently meeting or exceeding wholesaler demand for Mounjaro and Zepbound, and the company confirmed that it is not limiting the amounts that wholesalers can order. Lilly provided detailed information to FDA regarding the supply chain dynamics that can result in particular pharmacies being temporarily unable to buy these products from a distributor.[93] Most notably, Lilly described (b) (4)

[85] Id. at attachment 2.
[86] Id.
[87] Joint Status Report, *Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-00953-P, Dkt. 30, at 2 (N.D. Tex., Nov. 21, 2024).
[88] Oct. 2, 2024 email from Mark Boesen, Boesen & Snow Law, to Gail Bormel, FDA, "Tirzepatide Resolution," with attachment.
[89] Id.
[90] Id. at attachment.
[91] Nov. 15, 2024 Comment from FarmaKeio, Dkt. FDA-2015-N-0030. Tracking No. m3i-x61g-s9e4, with attachments.
[92] Id. at attachment. The submitted screenshots do not indicate the date; the comment's text and file names provide the only date information available.
[93] (b) (4)
[94] Id.

(b) (4)

As Lilly explained:

(b) (4)

In addition, Lilly provided additional explanation specific to the APC screenshots, (b) (4)

[7] Lilly also selected certain examples from the APC screenshots and (b) (4)

The limitations of the screenshot evidence, taken together and considered in light of Lilly's explanations, mean that the screenshots do not provide reliable evidence in assessing whether supply of Mounjaro and/or Zepbound is meeting demand. Accordingly, the screenshots do not undermine or outweigh the comprehensive information provided by Lilly regarding supply and demand – including supply in the wholesale portion of the distribution chain, discussed in section II.A above. Further, the pieces of evidence discussed in this section show at most only disconnected individual "snapshots" in time. The evidence provided by Lilly and analyzed above provides a much fuller picture of the supply and demand situation both over time, and at the national level. Lilly's evidence is therefore much more probative to the analysis FDA must conduct to determine the status of the shortage.

iii. Articles reported in the press and published on industry websites

FDA reviewed various articles and blog posts submitted by various groups, as well as other news coverage.[99] While these pieces discussed various aspects of the shortage situation, FDA did not find them to contain probative evidence relevant to the analysis FDA must conduct to determine whether a shortage has resolved. While some of these sources contained personal accounts of inability to get a particular product at a particular time, like the evidence discussed in sections

[95] Id.
[96] Id. at 9-10.
[97] Id. at 10-11.
[98] Id. at 10.
[99] *See*, *e.g.*, Appendix in Support of Plaintiff's Mot., *Outsourcing Facilities Ass'n*, No. 4:24-cv-00953-P, Dkt. 9 (Oct. 8, 2024) (identifying various articles, blog posts, and online discussions regarding availability of Mounjaro, Zepbound, and compounded tirzepatide).

II.B.1.i and ii above, those individual accounts do not undermine or outweigh the more specific, reliable, comprehensive, and current information that has been provided by Lilly demonstrating its ability to supply enough product to meet demand.

iv. Individual comments on Docket FDA-2015-N-0030

Thousands of individual comments discussing compounded GLP-1 drugs were recently submitted to FDA's compounding general docket, FDA-2015-N-0030.[100] Many of these comments are substantively identical. Each such commenter identifies themself as a patient "who has relied on compounded GLP-1 medications to effectively manage my health during the ongoing shortage of brand-name products from Eli Lilly and Novo Nordisk [the manufacturer of semaglutide]," and then includes a form letter asking FDA to "keep compounded GLP-1s available for patients."[101] The form letter does not specify whether the commenter uses tirzepatide, semaglutide, or both; nor does the form letter provide any specific evidence regarding inability to get a relevant product.[102] Like the evidence discussed in section II.B.1.i above, these comments do not provide reliable evidence that could be probative in assessing whether supply of Mounjaro or Zepbound is meeting demand on a nationwide scale, and they do not undermine or outweigh the more specific, reliable, comprehensive, and current information that has been provided by Lilly demonstrating its ability to supply enough product to meet demand.

v. Reports of "voluminous Tirzepatide compounding meeting high demand."

To the extent that stakeholders contend that the sales volume of compounded tirzepatide is *itself* evidence that the supply of Mounjaro or Zepbound is not currently keeping pace with demand for Mounjaro or Zepbound, FDA disagrees. The relevant demand here is the demand for the approved drug product,[103] and not the demand for a different drug, i.e., demand for a

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[100] For example, over three thousand posted comments are identical to docket no. FDA-2015-N-0030-8535, document ID FDA-2015-N-0030-8535.

[101] Id.

[102] Id.

[103] The FD&C Act requires FDA to maintain an up-to-date list of "drugs" in shortage, and defines a "drug shortage" as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." Sections 506E(a), 506C(h)(2), Section 506E(a). For this determination, when FDA applies the drug shortage definition to decide whether Lilly's tirzepatide injection products are in shortage, it cannot consider current demand for a compounded copy of these approved drugs part of the "demand" for the drug. The shortage definition requires FDA to determine whether demand or projected demand for a "drug" exceeds the supply of the "drug." If the compounded drug were considered the "drug" when FDA evaluates demand, then supply of the compounded drug would necessarily also be considered part of the "supply" of the drug under the statute– a nonsensical result that would upend the role of compounding during a shortage. It would mean, for example, that if outsourcing facilities began compounding a drug during the shortage of an approved drug, and the supply of the compounded drug combined with the supply of the approved drug were enough to meet demand, FDA would have to end the drug shortage – a decision that would end the outsourcing facility's ability continue compounding the drug and restart the shortage. (Under section 503B of the Act, outsourcing facilities may compound drugs that are identical or nearly identical to an approved drug while the approved drug is on FDA's drug shortage list; but must stop when the shortage ends.). Similarly, if section 503A compounding could end a shortage, that would call into question the ability of the section 503A compounders to continue "regularly" compounding drugs to address an ongoing shortage of an approved drug. *See* section 503A(b)(1)(D) (compounder may not compound drugs that are essentially a copy

compounded tirzepatide drug. Therefore, the information provided by Lilly relating to supply and demand for its Mounjaro and Zepbound products discussed above is the most relevant information to the 'current demand' aspect of the shortage determination. For example, Lilly's ability to fill orders from distributors most directly demonstrates that supply is currently meeting demand. With respect to compounded products, the submitted evidence does not demonstrate that patients seeking compounded tirzepatide are doing so *because* the approved products are in shortage. Patients may seek the compounded drug for many reasons, including differences in price or formulation, insurance coverage decisions, prescriber preferences, marketing efforts, and other reasons. Therefore, we consider the volume of compounding in itself to be of minimal relevance to the assessment of current demand. (By contrast, above in section II.B.1.i, we considered reports that consumers did, in fact, demand Lilly's approved products but were unable to obtain them.) We do, however, consider information the agency has received about the volume of compounding below, in section II.B.2., as part of our evaluation of *projected* demand for Lilly's pen products, which among other things considers the possible effect of the curtailing of compounding on demand for Lilly's products in the future.

2. Information about compounded drug products regarding projected demand

FDA's drug shortage decision focuses on whether the demand or projected demand for the FDA-approved tirzepatide injection products within the United States exceeds supply. However, FDA also considered the information it has received about the availability of, and demand for, compounded tirzepatide injection products insofar as that information may bear on projected demand for the FDA-approved products. FDA is aware that some patients and health care professionals have looked to unapproved, compounded tirzepatide injection products while the FDA-approved drug products were in shortage and while FDA has announced a period of intended enforcement discretion involving such compounded products.[104] We acknowledge reports of significant compounding, and that curtailing of such compounding is likely to have some effect on the demand for Lilly's products in the future. However, the agency does not have a sufficient, reliable basis to project the scope of this effect, and finds that, especially when weighed against the information provided by Lilly, it does not support a conclusion that as a result, projected demand will exceed Lilly's significant supply capacity.

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of a commercially available drug regularly or in inordinate amounts). Congress surely did not intend for this result. Therefore, it follows that, when evaluating "supply" and "demand" for Lilly's approved tirzepatide injection products previously on the drug shortage list, FDA must evaluate supply and demand for the approved drug, and not include demand and supply for compounded drugs that are essentially copies of those drugs.

[104] *See* Defendants' Unopposed Motion for Voluntary Remand and Stay, *Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-953, ECF No. 27, at 3. *See also* Letter from Gail Bormel, Office Director, CDER Office of Compounding Quality and Compliance, to Scott Brunner, APC (Oct. 17, 2024), available at https://www.fda.gov/media/182948/download?attachment. Generally, when an FDA-approved drug product is on FDA's drug shortage list, some federal law restrictions do not apply, such as, in certain circumstances, restrictions on compounding drugs that are essentially copies of approved drugs. Although compounded drug products can serve an important patient need, they also pose a higher risk to patients than FDA-approved drug products. Compounded drug products are not FDA-approved, which means they are not reviewed by FDA for safety, effectiveness, or quality before they are marketed. Therefore, approved drug products should be used to treat patients whenever possible.

503B Compounding. FDA by law receives some drug production information from outsourcing facilities,[105] which are required to report semi-annually on the quantity of drugs they compounded.[106] The data reported for the first half of 2024, which is the most recent complete reporting period, indicate that limited quantities of tirzepatide injection products were being compounded relative to production levels for the approved drug.

Table 7. Outsourcing facility reports, first six months of 2024[107].

Establishment	Active Ingredients Info	Package Description	Packages Produced
Mark Cuban Cost Plus Manufacturing and Compounding LLC (118916218)	2.5 mg/0.5 mL	2 mL in 1 VIAL, MULTI-DOSE	(b) (4)
PQ Pharmacy LLC (117479731)	10 mg/1 mL	1 mL in 1 VIAL, MULTI-DOSE	(b) (4)
Mark Cuban Cost Plus Manufacturing and Compounding LLC (118916218)	15 mg/0.5 mL	2 mL in 1 VIAL, MULTI-DOSE	(b) (4)
PQ Pharmacy LLC (117479731)	20 mg/1 mL	1 mL in 1 VIAL, MULTI-DOSE	(b) (4)
Olympia Pharmacy (017674368)	25 mg/1 mL	3 mL in 1 VIAL	(b) (4)

While we do not know how these products were prescribed, assuming that patients were expected to take 0.5mL in each dose, as with the approved drug, the reported production would represent (b) (4) doses over six months, or an average of (b) (4) doses per month. More recently, one outsourcing facility has stated that it compounded approximately (b) (4) mL of tirzepatide in September 2024,[108] which would represent (b) (4) doses if we assume, again, that there is 0.5mL per dose,[109] and OFA has represented that "OFA members have produced hundreds of thousands of doses of compounded tirzepatide in September 2024."[110] Even assuming that all of these doses have been supplied to the market and, upon the curtailing of compounding, would translate to demand for Lilly's products, this would represent a very small amount relative to Lilly's production and inventory. (b) (4), Lilly reported that it

[105] Section 503B of the FD&C Act (21 U.S.C. 353b) describes the conditions that must be satisfied for human drug products compounded in an outsourcing facility to be exempt from certain sections of the FD&C Act. Bulk drug substances used to compound a drug that is not on FDA's drug shortage list must be on a list of bulk drug substances established by the Secretary for which there is a clinical need (the 503B Bulks List). *See* section 503B(a)(2)(A) of the FD&C Act. Outsourcing facilities may not compound a drug that is essentially a copy of one or more FDA approved drugs, and under the applicable statutory definition, a drug compounded by an outsourcing facility is essentially a copy of an approved drug unless the approved drug is on FDA's drug shortage list at the time the compounded drug is compounded, distributed, and dispensed. *See* sections 503B(a)(5) and (d)(2) of the FD&C Act.

[106] Outsourcing facilities register with FDA (see section 503B(b)(1) of the FD&C Act) and report semi-annually on the drug products they compound (see section 503B(b)(2) of the FD&C Act).

[107] The Outsourcing Facility Product Report database is available at https://dps.fda.gov/outsourcingfacility. The number of packages produced is available in each facility's product reports.

[108] Declaration of Dan DeNeui, at 3 (App. 3) ¶ 15, *Outsourcing Facilities Ass'n v. FDA* (N.D. Tex. Oct. 8, 2024) (No. 4:24-cv-953) ECF No. 9.

[109] Based on the information FarmaKeio provided, this may represent fewer doses. FarmaKeio noted that tirzepatide injection products are dosed weekly (approximately 4 times a month) and that the varied weekly dosing of tirzepatide supplied approximately (b) (4) patients, *see id.*, which suggests a figure under (b) (4) doses.

[110] Declaration of Lee Rosebush, at 9 (App. 13) ¶ 39, *Outsourcing Facilities Ass'n v. FDA* (N.D. Tex. October 8, 2024) (No. 4:24-cv-953) ECF No. 9.

is able to supply (b) (4) per month, and its most recent stock report shows that its current autoinjector inventory contains (b) (4) and (b) (4) [111]

503A Compounding. State-licensed pharmacies compounding drugs under section 503A are primarily regulated by the states, and generally do not register with FDA or report to FDA the quantity or characteristics of the drugs they compound. FDA has been contacted by compounding trade associations and other companies involved in the marketing of compounded tirzepatide products, who have made multiple submissions contending that a substantial volume of compounding has been occurring in 503A facilities. While we acknowledge that compounding is occurring in section 503A facilities, most of these submissions have serious limitations. For example, OFA has directed FDA to news articles from June 2024 which reported that large compounding pharmacies may be "provisioning up to 2 million American patients with regular doses of semaglutide… or tirzepatide."[112] However, the articles do not provide support for this estimate[113] or provide enough detail for meaningful evaluation. For example, the articles do not separately estimate quantities for semaglutide and tirzepatide compounding, even though semaglutide compounding apparently represents a substantial part of the GLP-1 drug compounding,[114] and they do not present information about different strengths. The trade

[111] (b) (4)

[112] Arthur Allen, "Why Millions Are Trying Alternatives to Big Pharma's Weight Loss Drugs." July 20, 2024, *CBS News Health Watch*. Plaintiffs' Exhibit 6, *Outsourcing Facilities Ass'n v. FDA* (N.D. Tex. October 8, 2024) (No. 4:24-cv-953) ECF No. 9. This story was republished by *KFF Health News* under the same title on July 23, 2024, Plaintiffs' Exhibit 7, *Outsourcing Facilities Ass'n v. FDA* (N.D. Tex. October 8, 2024) (No. 4:24-cv-953) ECF No. 9; and a similar story appeared as: Arthur Allen, Copycat weight-loss drugs are major players with consumers," *Washington Post*, July 31, 2024, Plaintiffs' Exhibit 8, *Outsourcing Facilities Ass'n v. FDA* (N.D. Tex. October 8, 2024) (No. 4:24-cv-953) ECF No. 9. *See also* Patrick Wingrove and Bhanvi Satija, "Americans hungry for weight-loss drugs grapple with supply and insurance hurdles," Reuters, Nov. 4, 2024 (Reporting an analyst's estimate that "based on his conversations with compounding experts, as many as 2 million people in the U.S. could be taking compounded versions of the weight-loss drugs," but also stating that pharmacies were selling more compounded semaglutide than tirzepatide, and that "[a]nalysts have struggled to estimate the size of the compounded market for weight-loss drugs because their sale is not tracked in traditional channels. They are not covered by healthcare insurance plans and the pharmacies that make them do not have to report everything to the FDA."), available at https://www.reuters.com/business/healthcare-pharmaceuticals/americans-hungry-weight-loss-drugs-grapple-with-supply-insurance-hurdles-2024-11-04/.

[113] The reporter for the stories OFA cited said the estimate was based on interviews with "industry officials." Plaintiffs' Exhibit 6, at 2 (App. 51), *Outsourcing Facilities Ass'n v. FDA* (N.D. Tex. October 8, 2024) (No. 4:24-cv-953) ECF No. 9. One of these officials, the CEO of a compounding firm, frankly acknowledged that "no one … is tracking sales in the industry", and that his estimate of the market share for compounded GLP-1 products was "a "wild ballpark figure." *Id.* at 4 (App. 53).

[114] Available information does not allow FDA to make a reliable estimate of market share for compounded semaglutide and tirzepatide products, although there are many indications that compounded semaglutide has a substantial share of this market. As noted, *see* footnote 112, the Wingrove and Satija article reports that online pharmacies like Noom and Hims & Hers "are selling versions of Wegovy [semaglutide] *and to a lesser extent*, Zepbound…". (Emphasis added.) This is consistent with more recent reports indicating that Hims & Hers does not market a compounded tirzepatide product, and that another online marketer of weight loss drugs, Ro, has stopped selling compounded tirzepatide products, and agreed to begin selling Lilly's approved Zepbound vial products. *See* Sneha S.K., "Lilly to offer single-dose vials of weight-loss drug on telehealth platform Ro," Reuters, Dec. 11, 2024, available at https://www.reuters.com/business/healthcare-pharmaceuticals/telehealth-firm-ro-provide-single-dose-vials-lillys-zepbound-obesity-patients-2024-12-11; Elaine Chen and Katie Palmer, "Eli Lilly strikes Zepbound deal with Ro, amid questions about future of compounded GLP-1s," STAT+ Pharma, Dec. 11, 2024, available at https://www.statnews.com/2024/12/11/eli-lilly-zepbound-ro-health-agreement-weight-loss/.

associations and industry also submitted complaints they have collected from people reporting they have had difficulty accessing compounded drugs; the many difficulties of relying on such reports to ascertain the volume of compounding have been described above in section II.B.1.i.

On December 17, 2024, the Association for Pharmacy Compounding (APC) submitted a letter stating that its analysis of dispensing data from forty compounding pharmacies indicates that they had "collectively dispensed 125,000 compounded tirzepatide prescriptions over the past month….", and that these forty pharmacies represent "a fraction of compounders preparing these medications."[115] We acknowledge that a substantial volume of compounding of tirzepatide injection products is currently ongoing. However, if we assume for purposes of this decision that the quantities reported by APC are accurate, and add them to the quantities reported by OFA, the total amount remains small relative to Lilly's production and inventory. We acknowledge APC's statement that additional compounding is occurring beyond what it has identified. However, APC has not provided information that would help inform a different estimate.

Moreover, it is not clear how many patients currently using a compounded tirzepatide injection product will choose to switch to Lilly's approved pen products when compounding is curtailed. That is, it is not reasonable to project that demand for compounded products will appear in the future one-for-one as demand for Lilly's approved autoinjector pen products. *First*, OFA and APC, among others, have indicated on many occasions that unapproved, compounded products are less expensive than Lilly's approved pen products.[116] Future demand is likely to be affected by the prices consumers face, and it is difficult to predict how many patients purchasing compounded tirzepatide injection at current price points will switch to the approved Lilly autoinjector pen products at future price points, or to competitor products at their price points. We note, for example, that Lilly has begun direct marketing of Zepbound 2.5mg and 5mg vials (which have not been in shortage), at prices that are substantially lower than its autoinjector product, and recently reached agreement with a large telehealth organization (which previously distributed compounded tirzepatide drugs) to sell Lilly's vial product. (b) (4)

In addition, because the approved semaglutide products received approval earlier than tirzepatide, they have had more time to build recognition and acceptance. For Q3 2024, Novo Nordisk reported sales of Wegovy and Ozempic roughly double those of Lilly's Zepbound and Mounjaro. *See* "Lilly reports Q3 2024 financial results highlighted by strong volume-driven revenue growth from New Products," dated Oct. 30, 2024, available at https://investor.lilly.com/news-releases/news-release-details/lilly-reports-q3-2024-financial-results-highlighted-strong; Novo Nordisk "Financial report for the period 1 January 2024 to 30 September 2024," available at https://ml-eu.globenewswire.com/Resource/Download/11f24e9a-5374-4abf-afc1-a31bc257a98a. The above data and information do not allow for an estimate of market share for compounded tirzpetide and semaglutide, but do illustrate why aggregated estimates of *GLP-1* compounding should not be considered estimates of *tirzepatide* compounding.

[115] Tenille Davis to Robert Califf et al, Dec. 17, 2024, at 1.

[116] E.g., Jensen to Thakur et al., Sept. 9, 2024; DeNeui Declaration, paragraph 10 ("compounding pharmacies have provided doses of Tirzepatide at substantially lower costs, such as one-half or even one-quarter the cost of brand-name alternatives"); Declaration of Lee Rosebush, submitted in *Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-953, ECF Nos. 27, 28 (N.D. Tex.), paragraph 13 ("Patients report that they will continue using compounded versions of Tirzepatide for as long as possible because the cost is substantially lower"). While FDA recognizes the importance of prices to patients and the hardships that can be caused by higher prices, the drug shortage and compounding authorities in the FD&C Act require FDA to consider the supply of and demand for the approved drug in shortage.

(b) (4).[117] *Second*, we have received reports asserting that compounded products are in some cases promoted for uses that differ from the labeled indications of the approved drugs, such as for use for weight loss for patients who are not obese.[118] FDA has not made a finding that tirzepatide products are safe and effective for such uses, and if tirzepatide for these uses is not covered by insurance, consumers currently taking a compounded drug for such uses may decide not to purchase the approved drug when compounding of tirzepatide is curtailed. *Third*, an unknown quantity of compounded tirzepatide products have differences in formulation from the approved drug.[119] We do not know, and have no basis to reliably forecast, how many patients currently receiving these compounded drugs will choose to take up the approved drug. *Fourth,* it cannot be known at this time how regulatory decisions may affect the supply of other GLP-1 agonists when compounding is curtailed, or what marketing decisions other manufacturers may make to the curtailment of compounding. For all of these reasons, there remains considerable uncertainty about how future demand may increase due to patients who currently use compounded tirzepatide products switching to Lilly's approved pen products when compounding is curtailed.

Balanced against these uncertainties about projected demand, as described in section II.A. above, Lilly's supply of its pen products is currently meeting or exceeding demand, and Lilly credibly represents that it is able to manufacture (b) (4) of its tirzepatide injection products each month. Lilly also has substantial inventories of its approved pen products and vials and a larger volume of semi-filled syringes that can be packaged and relabeled quickly, and has demonstrated the ability to monitor supply and demand to rebalance production as needed. The company specifically projects that it will be able to continue meeting demand over the coming months, as it has been doing over the past few months.

Taking the available information together, while we recognize that significant compounding of tirzepatide injection products is occurring, and that some patients currently receiving those products can be expected to seek Lilly's approved products at a future point when compounding is curtailed, based on our best judgment and looking at the available information with its limitations, we conclude that Lilly's supply will meet or exceed projected demand.

Lilly has agreed to submit supply and demand information to the FDA every two weeks, and the agency will closely monitor supply and demand over the coming months. FDA will also continue to expedite review of applications that Lilly submits, if any, if we determine they could help prevent a future shortage, for example, by increasing Lilly's capacity to supply its tirzepatide

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117 (b) (4)

118 (b) (4), (b) (6)

119 For example, while APC recently reported a quantity of "tirzepatide prescriptions" that were dispensed, it did not provide more information about the products that were compounded. Davis to Califf et al, Dec. 17, 2024, at 1, Similarly, OFA reported a quantity of "compounded tirzepatide" made by its members, without detail. See Declaration of Lee Rosebush, at 9 (App. 13) ¶ 39, Outsourcing Facilities Ass'n v. FDA (N.D. Tex. October 8, 2024) (No. 4:24-cv-953) ECF No. 9. These do not indicate whether the compounded products have changes from the approved drug. We have received information that some compounders are preparing tirzepatide drug products in oral and sublingual dosage forms, or have been modifying the product formulation, e.g., by adding vitamin B12 or glycine. See (b) (4), (b) (6) *See also* FDA Warning Letter to Veronvy, December 10, 2024 (regarding "Elily Veronvy" and "Elily Veronvy 40+" drops), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/veronvy-694688-12102024.

injection products.[120] If in the future, nationwide demand exceeds supply (whether because of a higher than anticipated volume of patients seeking Lilly's products after compounding is curtailed or otherwise), FDA will return tirzepatide injection products to the drug shortage list.

In addition, the enforcement discretion period we describe below should provide an additional period for an orderly transition of patients currently taking compounded tirzepatide to seek and receive prescriptions for the approved product, which we expect to avoid unnecessary disruption to patient treatment and to help facilitate an orderly transition.

3. Other information

In some cases, FDA may consider IQVIA National Sales Perspectives data when evaluating supply and demand of a drug. IQVIA data is available from a private company that reports information, for covered entities, on the sales volume of prescription drug products moving from distributors and manufacturers into various outlets within the retail and non-retail markets.[121] These data can provide a signal about supply conditions in some cases. For example, if a drug that has established a consistent baseline of sales goes into shortage, the return of sales to the previously established baseline may suggest that supply has recovered. However, the tirzepatide injection products we consider here did not have a stable baseline, because the shortage was due to increased demand, so there is no baseline to compare. More generally, these sales data have important limitations for making the drug shortage determination. For example, IQVIA only covers part of the market, and even if there are changes in sales levels, these may not reflect changes in supply available from the manufacturer. We do ascertain through review of the data that sales are increasing, consistent with Lilly's reports.

Furthermore, although FDA does not commonly review data on prescription dispensing, reversals, and rejections when analyzing whether a drug is in shortage, in October we did review such data from a third party, Symphony Health's Metys database, to consider whether it might be useful with respect to tirzepatide injection products. We concluded that these data have very limited utility. They only provide information for about half of outpatient prescriptions, and with respect to those prescriptions, ambiguous information about supply and demand.[122] These data are not inconsistent with our conclusions about supply and demand as they have been trending consistently to the IQVIA sales data and Lilly's reports.

FDA also received a comment recommending that we consider tirzepatide injection products to be in shortage because on November 26, 2024, HHS issued a proposed regulation that, if

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120 (b) (4)

121 IQVIA, Available IQVIA Data, https://www.iqvia.com/insights/the-iqvia-institute/available-iqvia-data.

122 For example, while the data provide information about prescription reversals (where a prescription presented to a pharmacy is not picked up and is therefore closed out), the data did not reveal the reason – for example, whether the patient abandoned the prescription due to the co-pay, or had the prescription filled at another pharmacy that offered a lower price or more convenient location, or because the patient decided not to take the drug. And, to the extent the prescription was not picked up due to supply at a pharmacy, whether that was due to factors unrelated to supply in the United States – e.g., business decisions made by distributors or retailers about how much product to stock - rather than nationwide supply conditions. See Memo from Grace Chai, Jing Xu, Sonal Goyal, Corrine Woods, through Gerald Dal Pan, to CDER, October 23, 2024, "Injectable Semaglutide and Tirzepatide Prescription Transaction Data."

finalized in current form, would expand Medicare Part D and Medicaid coverage for GLP-1 products.[123] However, the rule was proposed for contract year 2026.[124] It is not clear how the market for GLP-1 or related drugs will change before then, or what supply conditions will be if the rule takes effect for contract year 2026. Additionally, this is a proposed rule in an early stage of development; the period for public comment is open through January 27, 2025. It is not yet clear whether the proposal will be finalized in current form, or if it will be modified or withdrawn. Accordingly, we do not consider the proposed rule to be a basis for considering tirzepatide injection products currently in shortage and will monitor the rulemaking and related developments.

III. Status of compounding following this decision

In connection with the litigation noted above,[125] FDA stated that during the reevaluation and for a period after the Agency makes its decision, FDA does not intend to take action against compounders for violations of the FD&C Act arising from conditions that depend on tirzepatide injection products' inclusion on FDA's drug shortage list, i.e., section 503A(b)(1)(D) (compounded drugs that are essentially a copy of a commercially available drug product) or sections 503B(a)(2)(A) (bulk drug substances used in compounding) and (a)(5)) (compounded drugs that are essentially a copy of an FDA-approved drug product).

In addition to that representation, as explained further below, to avoid unnecessary disruption to patient treatment and to help facilitate an orderly transition, for the same violations described above, FDA does not intend to take action against a compounder that is not registered as an outsourcing facility for compounding, distributing, or dispensing tirzepatide injection products that are essentially a copy of a commercially available drug product[126] within 60 days of this decision. In addition, FDA does not intend to take action against an outsourcing facility for use of the bulk drug substance tirzepatide to compound, distribute, or dispense a drug product that appeared on FDA's drug shortage list,[127] or for compounding, distributing, or dispensing tirzepatide injection products that are essentially a copy of an FDA-approved drug product,[128] within 90 days of this decision.

Neither FDA's statements in the court case, the court's order, nor this decision prevents FDA from taking action for violations of any other statutory or regulatory requirements, such as to address findings that a product may be of substandard quality or otherwise unsafe.

The enforcement discretion described here is based on the following considerations.

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[123] Email from Lee Rosebush to Gail Bormel et al., Nov. 26, 2024.
[124] *See* 89 F.R. 237 (Dec. 10, 2024).
[125] *See* Defendants' Unopposed Motion for Voluntary Remand and Stay, *Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-953, ECF No. 27, at 3. *See also* Letter from Gail Bormel, Office Director, CDER Office of Compounding Quality and Compliance, to Scott Brunner, APC (Oct. 17, 2024), available at https://www.fda.gov/media/182948/download?attachment.
[126] See section 503A(b)(1)(D) of the FD&C Act.
[127] See section 503B(a)(2)(A) of the FD&C Act.
[128] See section 503B(a)(5) of the FD&C Act.

First, as explained in FDA's guidance documents, "Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act" and "Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act," the FD&C Act generally limits the compounding of drugs that are essentially copies of commercially available and approved drugs, respectively.

Although compounded drug products can provide treatment options for patients during a drug shortage, compounded drugs have not undergone FDA premarket review for safety, effectiveness, and quality, and lack a premarket inspection and finding of manufacturing quality that is part of the drug approval process. Further, drug products that meet the conditions under section 503A are not subject to CGMP requirements and are subject to less robust production standards that provide less assurance of quality. Accordingly, the statute includes restrictions on compounding drugs that are essentially copies of commercially available drugs[129] and approved drug products that are not on FDA's drug shortage list. These restrictions help reduce the risk that compounders will prepare these unapproved drug products for patients whose medical needs could be met by an approved product. This helps to protect patients from unnecessary exposure to drugs that have not been shown to be safe and effective, and that offer fewer assurances of manufacturing quality.

The copies restrictions also protect the integrity of the new drug and abbreviated new drug (ANDA) approval processes by, for example, incentivizing sponsors to invest in and seek approval of innovative, life-saving medications - by limiting the ability of compounders to, after a drug is approved, compound "substitutes" that may be less expensive because they have not had to demonstrate safety and effectiveness or be labeled with adequate directions for use, and, for drugs compounded under section 503A, are not produced in accordance with CGMP requirements.[130]

For the above reasons, an indefinite or overly long period of enforcement discretion for continued compounding of drugs that may be essentially copies of an approved drug that is no longer in shortage would not be appropriate.

FDA has also considered public health concerns and reliance interests (as discussed further below), and the enforcement discretion described here takes those concerns into account. FDA considers that the 60/90-day period described here will allow patients a reasonable amount of time to transfer their prescriptions, as needed, to different pharmacies to obtain the FDA-approved drug. Patients who used compounded tirzepatide injection products during the shortage may otherwise face gaps in their ability to access treatment.[131] The additional time will

[129] For purposes of section 503A, FDA does not consider a drug on FDA's drug shortage list to be "commercially available."

[130] Less directly relevant in this case, involving copies of sterile injectable products, the copies restrictions also help protect FDA's drug monograph process by limiting the ability of compounders to produce drugs without having to comply with monograph standards or CGMP requirements that apply to such products.

[131] See October 3, 2024, letter from Scott Brunner, APC, to OCQC (docket no. FDA-2015-N-0030, document ID FDA-2015-N-0030-8519), stating that a 60-day transition period "would allow for a smoother transition, giving pharmacies time to contact prescribers for updated prescriptions and to navigate insurance prior authorization processes" and "would prevent abrupt discontinuations in patient care that will undoubtedly result from the sudden

allow local pharmacies to adjust their stocking and ordering patterns to adjust to new patterns of patient demand, which should help to minimize local disruptions.[132]

FDA also recognizes that compounded versions of drugs on FDA's drug shortage list can provide an important treatment option to patients during the shortage, and that compounders who prepare such drugs may be holding finished, compounded products, or inputs to compounded drugs, when a shortage resolves and the approved drug is taken off FDA's drug shortage list. For example, the compounder may have compounded drugs that are essentially copies of the approved drug and be waiting for the results of sterility tests before releasing them. FDA is required by statute to maintain an "up-to-date list" of drugs in shortage, 21 U.S.C. § 356e(a), and does not give advance notice of its decisions to move drugs on and off the list. In recognition of this fact, FDA's guidance for outsourcing facilities has previously described a brief period of enforcement discretion at the end of a drug shortage to account for such materials to be sold off.[133]

The above considerations are particularly relevant to the tirzepatide injection products shortage. We note that the shortage was ongoing for some time,[134] and compounders and other stakeholders report that a significant amount of compounding has been occurring. Additionally, FDA's re-evaluation of the shortage decision in the context of litigation may have caused some uncertainty about whether or when compounded copies would leave the market, slowing market transition. A period of enforcement discretion should help facilitate an orderly transition, as the adjustments described above take place. Although the 60/90-day period described here is longer than the period previously described in FDA's guidance documents, we conclude that it is justified in light of the considerations described here, including the information FDA has reviewed in connection with the tirzepatide injection products shortage. That this period is relatively brief also mitigates concerns about potential effects on patients, the integrity of the drug approval process, and any reliance interests of the approved drug manufacturer. While the approved drug manufacturer may have an interest in FDA providing only the more limited enforcement discretion stated in the Agency's existing guidances, FDA has considered any such

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unavailability of compounded copies"; and October 7, 2024, letter from Scott Brunner, APC, and Ronna Hauser, SVP, Policy and Pharmacy Affairs, National Community Pharmacists Association, to FDA, DSS, and OCQC (docket no. FDA-2015-N-0030, document ID FDA-2015-N-0030-8520), stating that during a 60-day transition period, "prescriptions can be authorized for the FDA-approved products, coverage determinations made by insurance companies, and the FDA-approved products can be obtained by pharmacies to fill the prescriptions."

[132] FDA recognizes that local and regional conditions can make it difficult for patients to get a drug through their local pharmacies, even if that drug is not in a nationwide shortage. FDA's authorities relating to drug shortages are limited to shortages that exist "in the United States," that is, at the national level. Section 506E(a) of the FD&C Act. Thus, FDA does not treat local or regional supply disruptions the same way as the Agency treats national shortages.

[133] FDA's guidance for outsourcing facilities provides a period of enforcement discretion of 60 days for orders received during a drug shortage. See Guidance for Industry: Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act (Jan. 2018), at 8; Guidance for Industry: Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act (Jan. 2017), at 7. FDA's guidance document for section 503A compounders, Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act (January 2018) does not address FDA's enforcement policy for this provision at the end of a drug shortage. CDER is currently re-evaluating these policies pertaining to removal of compounded drugs from the market at the end of a shortage.

[134] Since December 15, 2022.

reliance interest and concludes that it is outweighed by the reasons discussed here that otherwise support this brief additional period of enforcement discretion.

The amount of time FDA intends to exercise enforcement discretion is longer for outsourcing facilities (90 days) than for those compounding under 503A (60 days) because:

- Drugs compounded in outsourcing facilities under section 503B provide more assurances of quality than drugs compounded under section 503A because they are made in facilities registered with FDA that are subject to FDA inspection and cGMP requirements.
- FDA understands that outsourcing facilities need to invest relatively more resources and time before they can produce product during a shortage because of these quality standards.

IV. Conclusion

For the reasons above, FDA determines that the shortage of tirzepatide injection products, which first began in December 2022, is resolved. FDA continues to monitor supply and demand for these products.

Exhibit 2

U.S. FOOD & DRUG ADMINISTRATION

December 19, 2024

Patty Donnelly, Ph.D.
Senior Vice President, Global Quality
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

Sent by e-mail

Declaratory Order: Resolution of Shortages of Tirzepatide Injection Products (Mounjaro and Zepbound)

Tirzepatide injection products were first added to FDA's drug shortage list on December 15, 2022. The Agency determined that the shortage was resolved and removed tirzepatide injection products from FDA's drug shortage list on October 2, 2024.[1] FDA has now reevaluated that decision.[2]

This order has been prepared to allow for its public disclosure. It does not include any of the confidential commercial information and/or trade secret information provided by Eli Lilly and Company that FDA analyzed for the purpose of making the determination set forth herein.

This order revokes and replaces FDA's October 2, 2024 decision on the same subject.

I. Determination

FDA determines that the tirzepatide injection product shortage is resolved. This determination is based on the analysis set forth in FDA's decision memorandum dated December 19, 2024, "Resolution of Tirzepatide Injection Product Shortage and Supply Status," (Decision Memorandum") and summarized below.

FDA is instructed to "maintain an up-to-date list of drugs that are determined by [FDA] to be in shortage in the United States,"[3] and a "shortage" is "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug."[4] Eli Lilly and Company ("Lilly"), the manufacturer of the relevant tirzepatide injection drug

[1] https://dps.fda.gov/drugshortages/resolved/tirzepatide-injection
[2] On October 7, 2024, FDA was sued in the U.S. District Court for the Northern District of Texas by the Outsourcing Facilities Association and North American Custom Laboratories, LLC d/b/a Farmakeio Custom Compounding regarding removal of tirzepatide injection from FDA's drug shortages list. On October 11, 2024, upon FDA's motion, a court order remanded the decision to the Agency for reevaluation. *See Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-953, ECF Nos. 27, 28 (N.D. Tex.).
[3] Section 506E(a) of the FD&C Act.
[4] Section 506C(h)(2) of the FD&C Act; 21 CFR 314.81(b)(3)(iii)(f).

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10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

products, has provided FDA with detailed information and data regarding its production and inventory of these drug products at various points in time, including stock reports that show quantities supplied and demanded, and inventory held in stock, for all strengths of these drug products; cumulative quantities supplied to and demanded by its customers in the year 2024; projected demand and supply in future months; and wholesaler inventory data, among other information. We conclude that the information and data Lilly has provided to FDA demonstrate that Lilly's supply is currently meeting or exceeding demand for these drug products, and that Lilly has developed reserves that it now holds in its finished product inventory, plus significant units of semi-finished product, and has scheduled substantial additional production over the coming months, such that supply will meet or exceed projected demand.

FDA has also considered potentially relevant information regarding the shortage determination from patients, healthcare providers, and others, including compounders, along with data from other sources that we independently identified. After carefully evaluating this information, we find that it has important limitations. We conclude that this information does not undermine or outweigh the evidence demonstrating that Lilly's supply is currently meeting or exceeding demand and that, based on our best judgment, it will meet or exceed projected demand.

For example, FDA received reports that some patients and pharmacists are not able to obtain the approved drugs, and that a substantial amount of tirzepatide compounding is occurring. The information provided in Lilly's submissions demonstrate that the company is currently meeting or exceeding demand for Mounjaro and Zepbound. That is not inconsistent with some, and even many, individuals having had some trouble getting prescriptions for the affected drugs filled over the course of the shortage, and some individuals may still be currently encountering such challenges, even though Lilly's supply is now meeting or exceeding demand nationally. In our assessment, intermittent challenges of this kind are most likely explained not by a continuing national shortage of supply, but by the practical dynamics of the portion of the supply chain between Lilly and the individual customers, including wholesale distributors and retailers. We recognize that significant compounding of tirzepatide injection products is occurring, and that some number of patients currently receiving those products can be expected to seek Lilly's approved products at a future point when compounding is curtailed. However, the additional information provided by patients, healthcare providers, and others, including compounders does not demonstrate that Lilly will be unable to meet projected demand, especially when weighed against the Lilly-provided data.

For all of these reasons and as explained further in the Decision Memorandum, we determine that the shortage is resolved. Our determination is based on our conclusions that supply meets or exceeds current demand, and that, based on our best judgment looking at the available information with its limitations, supply will also meet or exceed projected demand.

FDA will continue to monitor supply and demand for these products, and whether any tirzepatide injection products should be included on the drug shortage list in the future, as appropriate.[5]

[5] Notwithstanding resolution of the shortage, FDA understands that patients and prescribers may still see intermittent localized supply disruptions as the products move through the supply chain from the manufacturer to wholesale distributors and pharmacies.

This order also explains that, in addition to the representations FDA made regarding enforcement in October 2024 in connection with litigation,[6] FDA does not intend to take action against compounders for violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act) arising from conditions that depend on tirzepatide injection products' inclusion on the FDA drug shortage list (see section 506E of the FD&C Act) [i.e., section 503A(b)(1)(D) (compounded drugs that are essentially a copy of a commercially available drug product) or sections 503B(a)(2)(A) (bulk drug substances used in compounding) and (a)(5) (compounded drugs that are essentially a copy of an FDA-approved drug product)] for the following time periods from the date of this order:

- For state-licensed pharmacists or physicians compounding under section 503A of the FD&C Act, 60 calendar days from the date of this order, until February 18, 2025; and
- For outsourcing facilities under section 503B of the FD&C Act, 90 calendar days from the date of this order, until March 19, 2025.

II. Background

FDA maintains an up-to-date list of drugs that are determined by the Agency to be in shortage in the United States.[7] FDA's drug shortage list is publicly available on the Agency's website.[8] FDA's drug shortage list includes the names and National Drug Code (NDC) numbers for such drugs; the name of each applicant for such drugs, the reason for the shortage as determined by FDA, and the estimated duration of the shortage.[9]

In this context, a drug shortage means "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug."[10] As such, in determining whether a drug is in shortage for purposes of the FD&C Act, FDA evaluates the supply and demand or projected demand of the drug on a nationwide level, across the entire market, not at

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[6] *See* Defendants' Unopposed Motion for Voluntary Remand and Stay, *Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-953, ECF No. 27, at 3. *See also* Letter from Gail Bormel, Office Director, CDER Office of Compounding Quality and Compliance, to Scott Brunner, Chief Executive Officer, Alliance for Pharmacy Compounding (APC) (Oct. 17, 2024), available at https://www.fda.gov/media/182948/download?attachment.

[7] See section 506E(a) of the FD&C Act (21 U.S.C. 356e) and 21 CFR 314.81(b)(3)(iii)(*d*)(*1*). Manufacturers of certain prescription drug products must notify FDA of a permanent discontinuance in the manufacture of the drug product, or an interruption in manufacturing of the drug product that is likely to lead to a meaningful disruption in supply of that drug in the United States, and the reasons for such discontinuance or interruption. For the same drugs, manufacturers are also required to report a permanent discontinuance in the manufacture of an active pharmaceutical ingredient of the drug or an interruption in the manufacture of an active pharmaceutical ingredient likely to lead to a meaningful disruption in supply of the manufacturer's drug, and the reasons for the discontinuance or interruption. See section 506C of the FD&C Act and 21 CFR 314.81(b)(3)(iii).

[8] https://dps.fda.gov/drugshortages. See section 506E(c) of the FD&C Act and 21 CFR 314.81(b)(3)(iii)(*d*)(*1*).

[9] See section 506E(b) of the FD&C Act and 21 CFR 314.81(b)(3)(iii)(*d*)(*1*). FDA cannot disclose trade secret or commercial or financial information that is considered confidential or privileged. See sections 506C(d) and 506E(c)(2) of the FD&C Act and 21 CFR 314.81(b)(3)(iii)(*d*)(*2*). Additionally, FDA may choose not to make drug shortage information publicly available if FDA determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of drug products to patients). See section 506E(c)(3) of the FD&C Act and 21 CFR 314.81(b)(3)(iii)(*d*)(*2*).

[10] Section 506C(h)(2) (21 U.S.C. 356c) of the FD&C Act; see also 21 CFR 314.81(b)(3)(iii)(*f*).

the local level.[11] The Agency acknowledges that even when a shortage is considered resolved, patients and prescribers may still see intermittent localized supply disruptions as products move through the supply chain from the manufacturer and distributors to local pharmacies.

FDA receives input regarding drug shortages from numerous stakeholders, including manufacturers, patients, healthcare providers, and others, including compounders.[12] In particular, manufacturers are required to notify FDA about discontinuances and manufacturing interruptions pertaining to certain drugs pursuant to statutory and regulatory requirements,[13] and they may voluntarily provide additional information as relevant about quality issues, increases in demand, recalls, or other events (e.g., relevant supply and demand conditions).

Tirzepatide is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist. Mounjaro and Zepbound are the only FDA-approved tirzepatide products. Mounjaro (tirzepatide) injection, for subcutaneous use, is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Mounjaro is approved as pre-filled single-dose pens in several strengths (2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5 mg/0.5 mL, 10 mg/0.5 mL, 12.5 mg/0.5 mL, and 15 mg/0.5 mL). The Mounjaro pen products were approved by FDA in May 2022 (NDA 215866) and added to FDA's drug shortage list in December 2022 due to high demand. Mounjaro single-dose vial products in the same strengths were approved in a supplement to NDA 215866 in July 2023, but are not currently marketed in the United States and have not been on FDA's drug shortage list. Zepbound (tirzepatide) injection, for subcutaneous use, is indicated in combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition. Zepbound is also approved as pre-filled single-dose pens and single-dose vials in the same strengths as Mounjaro (2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5 mg/0.5 mL, 10 mg/0.5 mL, 12.5 mg/0.5 mL, and 15 mg/0.5 mL). The Zepbound pen products were approved by FDA in November 2023 (NDA 217806) and added to FDA's drug shortage list in April 2024 due to high demand. The Zepbound single-dose vial products were approved in a supplement to NDA 217806 in March 2024, but only the 2.5 mg and 5.0 mg strengths are currently being marketed in the United States. The Zepbound vial products have never been on the shortage list.

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[11] See FDA Strategic Plan for Preventing and Mitigating Drug Shortages (October 2013), available at https://www.fda.gov/media/86907/download. See also CDER's manual of policies and procedures on drug shortage management (MAPP 4190.1 Rev. 4), available at https://www.fda.gov/media/72447/download; and FDA's draft guidance for industry, *Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Products or Active Pharmaceutical Ingredients Under Section 506C of the FD&C Act* (February 2024), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-discontinuance-or-interruption-manufacturing-finished-products-or-active. This draft guidance, when finalized, will represent FDA's current thinking on this topic.

[12] FDA's website includes information about drug shortage notifications for industry and a public portal for patients, healthcare providers, and organizations to report new shortages, available at https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages.

[13] Section 506C(h)(2) of the FD&C Act; 21 CFR 314.81(b)(3)(iii)(f).

III. Procedural Considerations

This declaratory order is the product of an informal adjudication in which FDA evaluated the information available to the agency to make a determination of the relevant facts regarding the affected drug products, and applied the statutory standard for drug shortages to those facts. Under 5 U.S.C. 554(e) (section 5(d) of the Administrative Procedure Act (APA)), an agency, "in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty." The APA defines "order" as "the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rulemaking but including licensing." 5 U.S.C. 551(6). The APA defines "adjudication" as "agency process for the formulation of an order." 5 U.S.C. 551(7). FDA's regulations, consistent with the APA, define "order" to mean "the final agency disposition, other than the issuance of a regulation, in a proceeding concerning any matter . . . ." 21 CFR 10.3(a). Our regulations also define "proceeding and administrative proceeding" to mean "any undertaking to issue, amend, or revoke a regulation or order, or to take or not to take any other form of administrative action, under the laws administered by the Food and Drug Administration." 21 CFR 10.3(a). Moreover, our regulations establish that the Commissioner may initiate an administrative proceeding to issue, amend, or revoke an order. 21 CFR 10.25(b).

The statute does not explicitly provide the procedure FDA must use to make a determination regarding whether a drug product is in shortage, or whether such a shortage has resolved. As explained below, FDA has determined that its drug shortage authority is more compatible with adjudication than with rulemaking, and, consistent with the agency's past practice, FDA continues to implement this authority through adjudication. "The choice between rule-making or declaratory order is primarily one for the agency regardless of whether the decision may affect policy and have general prospective application." *Viacom v. FCC*, 672 F.2d 1034, 1042 (2d Cir. 1982). *See also SEC v. Chenery*, 332 U.S. 194, 203 (1947); *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759 (1969); *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974); *Almy v. Sebelius*, 679 F.3d 297, 303 (4th Cir. 2012); *City of Arlington, Texas v. FCC*, 133 S. Ct. 1863, 1874 (2013); *Qwest Servs. Corp. v. FCC*, 509 F.3d 531, 536– 37 (D.C. Cir. 2007) ("Most norms that emerge from a rulemaking are equally capable of emerging (legitimately) from an adjudication, and accordingly agencies have very broad discretion whether to proceed by way of adjudication or rulemaking" (internal citations and quotations omitted)). Courts "accord significant deference to an agency's characterization of its own action" when determining whether it is a rule or an order for APA purposes. *Am. Airlines, Inc. v. Dep't of Transp.*, 202 F.3d 788, 797–98 (5th Cir. 2000) (citing and quoting *British Caledonian Airways, Ltd. v. Civil Aeronautics Bd.*, 584 F.2d 982, 992 (D.C. Cir. 1978) ("In the present case we have, moreover, the Board's own assertion that its order is purely interpretive, and this contention in itself is entitled to a significant degree of credence.... While declaratory orders differ in some respects from interpretive rules, the same rationale should apply equally to an agency's characterization of one of its rulings as a declaratory order.")).

Making a determination regarding drug shortage status in a declaratory order issued as a product of informal adjudication is well within FDA's discretion under the FD&C Act and the APA.

Whether an affected drug product is (or is no longer) in shortage is a "concrete and narrow question[]"—in this case involving a drug product manufactured by a single pharmaceutical company—"the resolution[] of which would have an immediate and determinable impact on specific factual scenarios." *City of Arlington v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012); *see also Qwest Servs. Corp.*, 509 F.3d at 536–37; *Chisholm v. FCC*, 538 F.2d 349, 364–66 (D.C. Cir. 1976). FDA is issuing this declaratory order to remove uncertainty as to the status of the shortages of tirzepatide injection drug products, specifically, Mounjaro 2.5 mg, 5.0 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg; and Zepbound 2.5 mg, 5.0 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg.

This adjudication requires FDA to make determinations about the relevant facts, using the information available to the agency, and apply the statutory standard for drug shortages to those facts. Such applications of law to facts do not create new law and accordingly do not require FDA to engage in rulemaking, even if they include some amount of interpretation. "The feature which distinguishes declaratory orders and other interpretative rulings from those legislative rules which must conform with the procedures established by the APA for rulemaking is not the extent of their effect, but rather that the order or ruling *instead of creating new law serves only to clarify and state an agency's interpretation of an existing statute or regulation*." *British Caledonian Airways v. Civil Aeronautics Board*, 584 F.2d 982, 990 (D.C. Cir. 1978) (emphasis added); *see also Trans International Airlines v. Civil Aeronautics Board*, 432 F.2d 607, 612 n.9 (D.C. Cir. 1970) ("an interpretation of . . . regulations by . . . declaratory ruling . . . [is] well within the scope of the familiar power of an agency to interpret the regulations within the framework of an adjudicatory proceeding"). In addition, the temporary nature of a shortage determination is consistent with adjudication rather than rulemaking. *See Goodman v. FCC*, 182 F.3d 987, 994-5 (D.C. Cir. 1999) (upholding an order granting temporary waivers to companies who were not named parties in the proceeding, and contrasting the temporary nature of the waivers with a "general, prospective amendment" to existing rules as "a strong reason to conclude the proceeding was not a rulemaking").

The applicable statutory authorities are more consistent with adjudication than with rulemaking in part because "adjudicatory decisions are not subject to the APA's notice-and-comment requirements." *Blanca Telephone Co. v. FCC*, 743 F.3d 860 (D.C. Cir. 2014)). In rulemaking, however, the APA typically requires agencies to "give interested persons an opportunity to participate . . . through submission of written data, views, or arguments." 5 U.S.C. § 553(c). Notice to interested parties of their opportunity to do so requires the agency to "reveal[] for public evaluation" the "'technical studies and data' upon which the agency relies.'" *Chamber of Commerce v. SEC*, 443 F.3d 890, 899 (D.C. Cir. 2006) (quoting *Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991)). Under the APA, therefore, "[a]n agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary." *Solite Corp.*, 952 F.2d at 484 (quoting *Connecticut Light and Power Co. v. NRC*, 673 F.2d 525, 530–31 (D.C. Cir. 1982)). Put another way, rulemaking generally requires an agency to "afford interested parties an opportunity to challenge the underlying factual data relied on by the agency." *Chemical Mfrs. Ass'n v. EPA*, 870 F.2d 177, 200 (5th Cir. 1989) (citing *Air Products & Chemicals, Inc. v. FERC*, 650 F.2d 687, 700 n.17 (5th Cir. 1981)).

These notice-and-comment requirements are impossible to reconcile with the statutory provisions governing a drug shortage determination. To begin, take the statutory section titled "public availability," 21 U.S.C. 356e(c). First, section 356e(c)(3) explicitly provides FDA with discretion not to make *the very existence of a shortage* public. It states that FDA "may choose not to make information collected under this section [356e] publicly available . . . if [FDA] determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of drug products to patients)." The existence of a shortage itself, as well as factual information supporting the determination of its existence, is "information collected" under section 356e, and the fact of a shortage's existence (rather than any particular factual detail supporting the determination of a shortage) is the most obvious type of information that would be likely to cause hoarding when publicly announced. Knowledge that a shortage exists may foreseeably incentivize people to, for example, hoard product for their own or others' use (thereby avoiding disruption for some patients, but at the possible expense of other patients), or for financial gain (such as by selling the product at increased prices due to scarcity). The statutory provision giving FDA discretion to choose whether to make a shortage public based on these types of concerns is impossible to reconcile with a requirement that FDA conduct notice-and-comment rulemaking. In such a circumstance there could be no notice, no comment, and no public announcement of the decision itself. By contrast, FDA could act consistently with the provision through an adjudication process in which the agency made the necessary information available only to affected entities in the product's supply chain.

Second, a large amount of the information that FDA analyzes to determine the status of a drug shortage is the drug manufacturer's trade secret and/or confidential commercial information which FDA may not publicly disclose under applicable laws and regulations. This includes detailed information about current and future production, inventory, sales, and distribution. Such information is, in most cases, closely held by the submitting company, which considers the information privileged and confidential business information. Such information is exempt from the public disclosure provisions of the Freedom of Information Act (FOIA) by exemption 4, see 5 U.S.C. 552(b)(4), and may not be disclosed by FDA because of protections in the Trade Secrets Act, see 18 U.S.C. 1905, and FDA's regulations. *See*, *e.g.*, 21 C.F.R. 20.111(d)(3) (identifying "production, sales, distribution, and similar data and information" submitted voluntarily to FDA as "not available for public disclosure" subject to certain exceptions); 10.20(j)(2)(i)(d) (similar); and 20.61 (further detailing FDA's treatment of such information). In some cases, most, or even all, of the factual materials that FDA considered, and which therefore make up the administrative record, will be subject to disclosure-law protections. The statute's "public availability" section recognizes this reality and underscores that the requirement to publish the drug shortage list does not alter or amend the disclosure restrictions in 18 U.S.C. 1905 or 5 U.S.C. 552(b)(4); *see also* 21 U.S.C. 356e(c)(2); *Food Marketing Institute v. Argus Leader Media*, 588 U.S. 427, 440 (discussing sales data, and concluding that "where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of [5 U.S.C. 552(b)(4)]"). Because, absent the drug manufacturer's consent, FDA typically cannot proactively

publish confidential information about a drug's current and future production, inventory, sales, and distribution, notice and comment rulemaking is incompatible with drug shortage decisions.

Third, section 356e(c)(1)'s directive only that the agency "shall make the information in such list publicly available" (subject to the significant exceptions discussed immediately above) is more consistent with adjudication than rulemaking. The statute does not provide that the agency must use rulemaking, or that it must publish its determination in the Federal Register. The APA requires agencies to "make available for public inspection and copying" any "final opinions, . . . as well as orders, made in the adjudication of cases," 5 U.S.C. § 552(a)(2)(A), and if an order contains "statements of general policy or interpretations of general applicability," the agency may need to publish the order in the Federal Register, 5 U.S.C. § 552(a)(1)(D). But the Federal Register publication requirement does not apply to "interpretations of general applicability [made] in the course of issuing adjudicatory opinions" in light of section 552(a)(2), which requires only "public inspection and copying" of orders. *See*, *e.g.*, *Cheshire Hosp. v. New Hampshire-Vermont Hospitalization Serv.*, 689 F.2d 1112, 1123 (1st Cir. 1982) ("Courts which have been forced to harmonize these two provisions [§ 552(a)(1)(D) and § 552(a)(2)(D)] have held that an agency may formulate interpretations of general applicability in the course of issuing adjudicatory opinions without publishing such opinions in the Federal Register. The agency need only make such opinions available to the public as provided for by 5 U.S.C. s 552(a)(2)(A).") (internal citations omitted).

Beyond the "public availability" statutory section, the requirement in 21 U.S.C. 356e(a) that the Secretary maintain an "up-to-date" drug shortage list also, at a minimum, strongly suggests that the authority is more consistent with adjudication than with rulemaking. Even if notice and comment rulemaking were done expeditiously, that procedure plus a 30-day delayed effective date, *see* 5 U.S.C. § 553(b)-(d), would not result in a drug shortage list that could fairly be characterized as "up-to-date," thereby potentially preventing the agency from fulfilling its statutory mandate. While the APA contains a "good cause" exception to the notice-and-comment and 30-day delayed effective date requirements, 5 U.S.C. § 553(b)(B), (d)(3), the exception's requirements have been stringently interpreted, which could introduce uncertainty about whether a court will agree with the agency that good cause exists in a particular circumstance. *See, e.g., State of N. J., Dep't of Env't Prot. v. U.S. Env't Prot. Agency*, 626 F.2d 1038, 1045 (D.C. Cir. 1980) ("exceptions to the notice-and-comment provisions of section 553 will be narrowly construed and only reluctantly countenanced"). And even assuming that drug shortage decisions would routinely qualify for the good cause exception, the most straightforward interpretation is that Congress did not intend such decisions to be subject to notice-and-comment requirements at all, rather than that Congress intended such decisions to be subject to, but routinely exempt from, those requirements.

For all of these reasons, FDA considers the drug shortage list authority in 21 U.S.C. 356e to be much more compatible with adjudication than rulemaking, and consistent with its approach to date, the agency continues to choose to implement this authority through adjudication.

Finally, FDA notes that this order is a product of an informal adjudication that included notice to affected parties via publication of the shortage determination on FDA's website, and an

opportunity for affected parties to be heard by submitting information to the Agency for consideration. The APA gives agencies discretion to determine the appropriate level of public participation in agency decisions. *See* 5 U.S.C. 555(b) ("So far as the orderly conduct of public business permits, an interested person may appear before an agency. . . for the . . . determination of an issue"). Multiple interested parties, including the manufacturer of the affected drug products, individual patients, pharmacy compounders, outsourcing facilities, associations representing pharmacy compounders and outsourcing facilities, and telehealth companies, did in fact submit information to the Agency, both before FDA's initial announcement that these shortages had resolved and during FDA's reevaluation of that decision. The agency considered those submissions in formulating this order. Such procedures are appropriate for the formulation of declaratory orders and avoid the problems that would be presented by notice-and-comment rulemaking, as described above. *See*, *e.g.*, *National Labor Relations Board v. Bell Aerospace*, 416 U.S. 267, 295 (1975) (no procedural error where the parties "most immediately affected" by the order were "accorded a full opportunity to be heard").

IV. Status of Compounding Following this Decision

In connection with the litigation noted above,[14] FDA stated that during the reevaluation and for a period after the Agency makes its decision, FDA does not intend to take action against compounders for violations of the FD&C Act arising from conditions that depend on tirzepatide injection products' inclusion on FDA's drug shortage list, i.e., section 503A(b)(1)(D) (compounded drugs that are essentially a copy of a commercially available drug product) or sections 503B(a)(2)(A) (bulk drug substances used in compounding) and (a)(5)) (compounded drugs that are essentially a copy of an FDA-approved drug product).

In addition to that representation, as explained further below, to avoid unnecessary disruption to patient treatment and to help facilitate an orderly transition, for the same violations described above, FDA does not intend to take action against a compounder that is not registered as an outsourcing facility for compounding, distributing, or dispensing tirzepatide injection products that are essentially a copy of a commercially available drug product[15] within 60 days of this decision. In addition, FDA does not intend to take action against an outsourcing facility for use of the bulk drug substance tirzepatide to compound, distribute, or dispense a drug product that appeared on FDA's drug shortage list,[16] or for compounding, distributing, or dispensing tirzepatide injection products that are essentially a copy of an FDA-approved drug product,[17] within 90 days of this decision.

Neither FDA's statements in the court case, the court's order, nor this order prevents FDA from taking action for violations of any other statutory or regulatory requirements, such as to address findings that a product may be of substandard quality or otherwise unsafe.

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[14] *See* Defendants' Unopposed Motion for Voluntary Remand and Stay, *Outsourcing Facilities Ass'n v. FDA*, No. 4:24-cv-953, ECF No. 27, at 3. *See also* Letter from Gail Bormel, Office Director, CDER Office of Compounding Quality and Compliance, to Scott Brunner, APC (Oct. 17, 2024), available at https://www.fda.gov/media/182948/download?attachment.

[15] See section 503A(b)(1)(D) of the FD&C Act.

[16] See section 503B(a)(2)(A) of the FD&C Act.

[17] See section 503B(a)(5) of the FD&C Act.

The enforcement discretion described here is based on the following considerations.

First, as explained in FDA's guidance documents, "Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act" and "Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act," the FD&C Act generally limits the compounding of drugs that are essentially copies of commercially available and approved drugs, respectively.

Although compounded drug products can provide treatment options for patients during a drug shortage, compounded drugs have not undergone FDA premarket review for safety, effectiveness, and quality, and lack a premarket inspection and finding of manufacturing quality that is part of the drug approval process. Further, drug products that meet the conditions under section 503A are not subject to CGMP requirements and are subject to less robust production standards that provide less assurance of quality. Accordingly, the statute includes restrictions on compounding drugs that are essentially copies of commercially available drugs[18] and approved drug products that are not on FDA's drug shortage list. These restrictions help reduce the risk that compounders will prepare these unapproved drug products for patients whose medical needs could be met by an approved product. This helps to protect patients from unnecessary exposure to drugs that have not been shown to be safe and effective, and that offer fewer assurances of manufacturing quality.

The copies restrictions also protect the integrity of the new drug and abbreviated new drug (ANDA) approval processes by, for example, incentivizing sponsors to invest in and seek approval of innovative, life-saving medications - by limiting the ability of compounders to, after a drug is approved, compound "substitutes" that may be less expensive because they have not had to demonstrate safety and effectiveness or be labeled with adequate directions for use, and, for drugs compounded under section 503A, are not produced in accordance with CGMP requirements.[19]

For the above reasons, an indefinite or overly long period of enforcement discretion for continued compounding of drugs that may be essentially copies of an approved drug that is no longer in shortage would not be appropriate.

FDA has also considered public health concerns and reliance interests (as discussed further below), and the enforcement discretion described here takes those concerns into account. FDA considers that the 60/90-day period described here will allow patients a reasonable amount of time to transfer their prescriptions, as needed, to different pharmacies to obtain the FDA-approved drug. Patients who used compounded tirzepatide injection products during the

[18] For purposes of section 503A, FDA does not consider a drug on FDA's drug shortage list to be "commercially available."

[19] Less directly relevant in this case, involving copies of sterile injectable products, the copies restrictions also help protect FDA's drug monograph process by limiting the ability of compounders to produce drugs without having to comply with monograph standards or CGMP requirements that apply to such products.

shortage may otherwise face gaps in their ability to access treatment.[20] The additional time will allow local pharmacies to adjust their stocking and ordering patterns to adjust to new patterns of patient demand, which should help to minimize local disruptions.[21]

FDA also recognizes that compounded versions of drugs on FDA's drug shortage list can provide an important treatment option to patients during the shortage, and that compounders who prepare such drugs may be holding finished, compounded products, or inputs to compounded drugs, when a shortage resolves and the approved drug is taken off FDA's drug shortage list. For example, the compounder may have compounded drugs that are essentially copies of the approved drug and be waiting for the results of sterility tests before releasing them. FDA is required by statute to maintain an "up-to-date list" of drugs in shortage, 21 U.S.C. § 356e(a), and does not give advance notice of its decisions to move drugs on and off the list. In recognition of this fact, FDA's guidance for outsourcing facilities has previously described a brief period of enforcement discretion at the end of a drug shortage to account for such materials to be sold off.[22]

The above considerations are particularly relevant to the tirzepatide injection products shortage. We note that the shortage was ongoing for some time,[23] and compounders and other stakeholders report that a significant amount of compounding has been occurring. Additionally, FDA's re-evaluation of the shortage decision in the context of litigation may have caused some uncertainty about whether or when compounded copies would leave the market, slowing market transition. A period of enforcement discretion should help facilitate an orderly transition, as the adjustments described above take place. Although the 60/90-day period described here is longer than the period previously described in FDA's guidance documents, we conclude that it is justified in light of the considerations described here, including the information FDA has reviewed in connection with the tirzepatide injection products shortage. That this period is relatively brief

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[20] See October 3, 2024, letter from Scott Brunner, APC, to OCQC (docket no. FDA-2015-N-0030, document ID FDA-2015-N-0030-8519), stating that a 60-day transition period "would allow for a smoother transition, giving pharmacies time to contact prescribers for updated prescriptions and to navigate insurance prior authorization processes" and "would prevent abrupt discontinuations in patient care that will undoubtedly result from the sudden unavailability of compounded copies"; and October 7, 2024, letter from Scott Brunner, APC, and Ronna Hauser, SVP, Policy and Pharmacy Affairs, National Community Pharmacists Association, to FDA, DSS, and OCQC (docket no. FDA-2015-N-0030, document ID FDA-2015-N-0030-8520), stating that during a 60-day transition period, "prescriptions can be authorized for the FDA-approved products, coverage determinations made by insurance companies, and the FDA-approved products can be obtained by pharmacies to fill the prescriptions."

[21] FDA recognizes that local and regional conditions can make it difficult for patients to get a drug through their local pharmacies, even if that drug is not in a nationwide shortage. FDA's authorities relating to drug shortages are limited to shortages that exist "in the United States," that is, at the national level. Section 506E(a) of the FD&C Act. Thus, FDA does not treat local or regional supply disruptions the same way as the Agency treats national shortages.

[22] FDA's guidance for outsourcing facilities provides a period of enforcement discretion of 60 days for orders received during a drug shortage. See Guidance for Industry: Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act (Jan. 2018), at 8; Guidance for Industry: Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act (Jan. 2017), at 7. FDA's guidance document for section 503A compounders, Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act (January 2018) does not address FDA's enforcement policy for this provision at the end of a drug shortage. CDER is currently re-evaluating these policies pertaining to removal of compounded drugs from the market at the end of a shortage.

[23] Since December 15, 2022.

also mitigates concerns about potential effects on patients, the integrity of the drug approval process, and any reliance interests of the approved drug manufacturer. While the approved drug manufacturer may have an interest in FDA providing only the more limited enforcement discretion stated in the Agency's existing guidances, FDA has considered any such reliance interest and concludes that it is outweighed by the reasons discussed here that otherwise support this brief additional period of enforcement discretion.

The amount of time FDA intends to exercise enforcement discretion is longer for outsourcing facilities (90 days) than for those compounding under 503A (60 days) because:

- Drugs compounded in outsourcing facilities under section 503B provide more assurances of quality than drugs compounded under section 503A because they are made in facilities registered with FDA that are subject to FDA inspection and cGMP requirements.
- FDA understands that outsourcing facilities need to invest relatively more resources and time before they can produce product during a shortage because of these quality standards.

V. Conclusion

FDA has determined that the shortage of tirzepatide injection products, which first began in December 2022, is resolved. FDA continues to monitor supply and demand for these products.

Sincerely,

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

CC: Lee Rosebush, Chairman, Outsourcing Facilities Association

Dan DeNeui, Chief Executive Officer and Managing Partner of North American Custom Laboratories, LLC d/b/a FarmaKeio Custom Compounding

Scott Brunner, Chief Executive Officer, Alliance for Pharmacy Compounding

Exhibit 3

Alliance for Pharmacy Compounding

Compounding the Joy of Living®

October 12, 2024

Dr. Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

As we raised with you last week, the Alliance for Pharmacy Compounding has serious concerns about FDA's decision to abruptly remove tirzepatide from the agency's drug shortage list. A transitionary period is needed as patients taking compounded tirzepatide return to their prescriber for a new prescription and work with their pharmacies to access Mounjaro and Wegovy. Over the last ten days, pharmacies have been unable to source anywhere near the volume of Mounjaro and Wegovy needed to meet demand, and patient continuity of care has been jeopardized.

We took interest in the recent lawsuit filed by the Outsourcing Facilities Association against FDA for removing tirzepatide from the drug shortage list, as well as FDA's unopposed motion requesting a stay to the court proceeding and a remand back to the agency so that FDA can reconsider its decision. We were pleased that the court ordered the stay and remanded the case back to FDA.

Because the court order references FDA's intention not to take action against the case's plaintiffs while the reconsideration of the action is undertaken, there is confusion about how the order will be enforced. Can *all* outsourcing facilities and state-licensed pharmacies — not just the named plaintiffs of the lawsuit — resume compounding of tirzepatide pursuant to all relevant existing laws, regulations and agency guidance? 503As and 503Bs both are needed to meet the current demand and ensure patient continuity of care.

We respectfully request prompt action by FDA to reverse the decision to remove tirzepatide from the drug shortage list so that patient continuity of care is not disrupted further. We also ask that FDA provide written clarification that the agency will not take enforcement action against *any* outsourcing facility or state-licensed pharmacy otherwise lawfully compounding tirzepatide while FDA reconsiders its decision to remove the drug from the shortage list.

It is our hope that going forward, FDA will work more closely with hospitals, prescribers, pharmacies, and outsourcing facilities to better determine which drugs should be placed on or removed from the FDA Drug Shortage List. APC also hopes that FDA will consider providing guidance for industry establishing a transitionary period of enforcement discretion as high-demand drugs come off the shortage list to allow patients time to revisit their prescribers and source the FDA-approved versions of the drugs.

Thank you in advance for your prompt attention to this request. We are available to discuss this letter and the broader issue of maintaining patient access to drugs as they transition off the FDA Drug Shortage List.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer

Exhibit 4

NewsRoom

10/22/24 MarketLine Ind. NewsWire 14:33:00

MarketLine Industry NewsWire

October 22, 2024

MangoRx hits back at Eli Lilly's weight loss drug copycat claims

Eli Lilly sued three online vendors and medical spas earlier this week over improper copying of tirzepatide.

MangoRx said it "strongly refutes" claims made by Eli Lilly that it improperly copied blockbuster weight-loss medicines for sale on its telemedicine platform.MangoRx was responding to Eli Lily after the drugmaker sued it and two other medical spas and online vendors earlier this week for selling products claiming to contain tirzepatide, the active ingredient in Lilly's popular GLP-1 agonist drugs Zepbound and Mounjaro.MangoRx is one of those implicated in the lawsuits as first reported by Reuters, as it sells a compounded version of tirzepatide in a weight loss product called Trim. FDA-approved drugs can be compounded under certain conditions such as if the original approved drug is in shortage and unavailable. Many patients seeing GLP-1 agonists turned to compound pharmacies as demand for Zepbound and Novo Nordisk's Wegovy (semaglutide) far-outpaced supply, leading to shortages of the FDA-approved products. The FDA removed Lilly's tirzepatide from its drug shortage list on 2 October, removing the previous qualification granted to compounding pharmacies to manufacture copycats of the drugs.However, last week the FDA surprisingly said it would allow pharmacists to continue making compounded versions of tirzepatide while it reconsiders its decision to remove the drug from its nationwide shortage list. Compounders are still allowed to manufacture copycat versions of Wegovy, which is still on the shortage list.Eli Lilly, which has sued more than 20 medical spas, wellness centres, and compounding pharmacies over the past year, alleges MangoRx has improperly copied tirzepatide.According to MangoRx's website, Trim uses an "innovative formula, using the power of Tirzepatide" and "offers an effective and safe method for shedding excess weight." Eli Lilly claims there is no evidence that this compounded drug is safe and effective; the FDA has not approved an oral version of tirzepatide.MangoRx said it "has strong arguments against Eli Lilly's claims and intends to vigorously defend itself in this matter." The company added it remains committed to offering patients innovative care "while striving to comply with federal, state and local regulatory guidelines".Also involved in Eli Lilly's most recent filing, were Pivotal Peptides and Genesis Lifestyle Medicine, with both companies allegedly selling tirzepatide-containing products to patients. Eli Lilly is looking to protect one of its most prized assets, with global sales of Mounjaro/ Zepbound forecast to reach more than $32bn by 2030, as per analysis by GlobalData's Pharma Intelligence Center.GlobalData is the parent company of Pharmaceutical Technology.

---- Index References ----

Company: ELI LILLY AND COMPANY; PHARMA TECH RESEARCH CORP; NOVO NORDISK A/S

News Subject: (Major Corporations (1MA93))

Industry: (Drug Approval Process (1DR91); Drug Discovery & Development Process (1DR41); Pharmaceuticals (1PH33); Pharmaceuticals & Biotechnology (1PH13); Pharmaceuticals & Biotechnology Industry Highlights (1PH07); Pharmaceuticals Research & Development (1PH57))

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End of Document

NewsRoom

Exhibit 5

10/31/24 U-Wire 00:00:00

U-Wire

October 31, 2024

COLUMN | The Weight of Weight-Loss Drugs

Auburn University; Auburn, AL - opinion

By

Over the last few years, the medical world has seen a revolution in the treatment of diabetes and weight loss. What started as treatments for type two diabetes, medications like Semaglutide and Tirzepatide have since been approved by the FDA to treat obesity, offering hope to millions who have long struggled with being overweight due to conditions preventing them from seeing results purely through diet and exercise.

While these glucagon-like peptide-1 injections, or GLP-1s for short, have shown to be effective when taken by those who need it, their promise comes with a hefty price and several obstacles which make them inaccessible to the people who need them the most.

To start, these drugs aren't cheap. A month's supply can cost around $936 without insurance, and even for those with it, coverage is often limited as most insurers only approve these medications for diabetes. This leaves those prescribed a GLP-1 for weight loss purposes to cover the full cost out of pocket, but spending nearly a thousand dollars a month on medication isn't feasible for most of Americans' wallets.

This is especially troubling when you consider that these demographics are the ones who need access to these medications the most. Studies have shown that there exists a strong correlation between obesity and poverty, as healthy foods like fresh produce and lean proteins are often significantly more expensive than processed meals or fast food, and in recent years, these price gaps have only widened.

The lack of access to affordable, nutritious food can also contribute to long-term health problems like increased insulin resistance and high cholesterol down the road, both of which can be treated with GLP-1's, but, are out of reach for this group of people.

Pharmacies are experiencing a surge in demand for GLP-1 medications from those seeking quick weight loss, while celebrities and the wealthy often secure prescriptions through their connections without genuine medical need. These drugs have gained widespread attention in the media, with public figures like Chelsea Handler and Elon Musk openly admitting to using Ozempic and Wegovy, brand names for semaglutide and tirzepatide, respectively.

"My anti-aging doctor just hands [Ozempic] out to everyone," said Handler in an interview with Call Her Daddy host Alex Cooper.

The misuse of these drugs by individuals who don't medically need them has led to some unsettling side effects, including what's been dubbed "Ozempic face" by the online community, referring to the scrawny, aged appearance some celebrities have developed due to rapid weight loss, raising questions about the broader implications of using such powerful medications for purely cosmetic reasons.

This newfound attention has led to a surge in demand for these drugs for cosmetic purposes, creating strain on the supply chain that has only recently become more stable. As a result, prices have gone up and shortages have become more common, making it difficult for those with legitimate medical needs to access their prescriptions consistently. Many patients are now forced to ration their doses and scramble for refills before the drug goes out of stock again.

It's clear that significant changes are needed to make these drugs more accessible. Lawmakers need to push insurance companies to cover these medications for weight loss, not just diabetes. Obesity is a serious health condition, particularly for those with underactive thyroid glands and other endocrine disorders, and it deserves the same level of treatment and care.

With around 40% of U.S. adults classified as obese, the demand for affordable, effective treatment is evident. It's crucial that those who genuinely need these medications have access, especially when misuse by people without medical necessity further complicates supply issues.

Additionally, pharmaceutical companies need to address the supply chain issues and high out of pocket costs that have made these drugs so hard to come by for those who need them. Streamlining production processes and encouraging competition can help new medications enter the market and reduce costs. Regulatory measures should also be put in place to prevent companies from charging excessively for these drugs, especially since they can be produced for less than $5.

Public education about these medications is also essential. While the buzz around drugs like Mounjaro and Zepbound has grown significantly, many people still don't fully understand their intended purpose. These aren't miracle cures for losing a few pounds -- they're long-term treatments for people dealing with significant health issues tied to weight. By better educating the public, we can hopefully reduce the number of people using these drugs for cosmetic purposes and ensure that those who really need them have priority access.

The future of weight loss treatments looks promising, but only if we address the issues of affordability and access. With a more just distribution system, these groundbreaking drugs could genuinely transform lives and offer hope to those most susceptible to the challenges of being overweight.

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---- Index References ----

Company: Plainsman Mfg. Inc.; U.S. Food and Drug Administration; M2 COMMUNICATIONS LLC

News Subject: (General Interest Diabetes (1GE92); Health & Family (1HE30); Health & Wellness (1HE60); Obesity & Weight Control (1OB69))

Language: EN

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Word Count: 859

End of Document

Exhibit 6

01-Nov-2024

Cardinal Health, Inc. (CAH)

Q1 2025 Earnings Call

CORPORATE PARTICIPANTS

Matt Sims
Vice President-Investor Relations, Cardinal Health, Inc.

Jason M. Hollar
Chief Executive Officer & Director, Cardinal Health, Inc.

Aaron E. Alt
Chief Financial Officer, Cardinal Health, Inc.

OTHER PARTICIPANTS

Lisa C. Gill
Analyst, JPMorgan Securities LLC

Michael Cherny
Analyst, Leerink Partners LLC

Erin Wilson Wright
Analyst, Morgan Stanley & Co. LLC

Eric Percher
Analyst, Nephron Research LLC

Allen Lutz
Analyst, BofA Securities, Inc.

Kevin Caliendo
Analyst, UBS Securities LLC

Eric White Coldwell
Analyst, Robert W. Baird & Co., Inc.

George Hill
Analyst, Deutsche Bank Securities, Inc.

Stephanie July Davis
Analyst, Barclays Capital

Elizabeth Anderson
Analyst, Evercore ISI

Daniel Grosslight
Analyst, Citigroup Global Markets, Inc.

Charles Rhyee
Analyst, TD Cowen

Stephen Baxter
Analyst, Wells Fargo Securities LLC

MANAGEMENT DISCUSSION SECTION

Operator: Hello, and welcome to the First Quarter Fiscal Year 2025 Cardinal Health, Incorporated Earnings Conference Call. My name is George. And I'll be your coordinator for today's event. Please note this conference is being recorded, and for the duration of the call your lines will be in listen-only mode. However, you will have the opportunity to ask questions at the end of the presentation. [Operator Instructions]

I'd now hand the call over to your host today, Mr. Matt Sims, Vice President, Investor Relations. Please go ahead, sir.

Matt Sims

Vice President-Investor Relations, Cardinal Health, Inc.

Welcome to this morning's Cardinal Health first quarter fiscal 2025 earnings conference call, and thank you for joining us. With me today are Cardinal Health's CEO, Jason Hollar; and our CFO, Aaron Alt.

You can find this morning's earnings press release and investor presentation on the Investor Relations section of our website at IR.cardinalhealth.com. Since we will be making forward looking statements today, let me remind you that the matters addressed in the statements are subject to risks and uncertainties that could cause our actual results to differ materially from those projected or implied. Please refer to our SEC filings and the forward looking statements slide at the beginning of our presentation for a description of these risks and uncertainties. Please note that during our discussion today, the comments will be on a non-GAAP basis, unless specifically called out as GAAP.

GAAP to non-GAAP reconciliations for all relevant periods can be found in the supporting schedules attached to our press release. For the Q&A portion of today's call, we kindly ask that you limit questions to one per participant so that we can try and give everyone an opportunity.

With that, I will now turn the call over to Jason.

Jason M. Hollar

Chief Executive Officer & Director, Cardinal Health, Inc.

Thanks, Matt. Good morning everyone. Overall Cardinal Health delivered a terrific start to fiscal 2025 with strong operational and financial performance led by Pharma and Specialty Solutions. The ongoing strength and resiliency of our largest and most significant business was evident, delivering 16% segment profit growth, reflecting the team's advanced preparations and excellent execution in managing through the previously communicated large customer transition. We continue to operate in a stable industry environment with positive utilization trends underpinning our growth.

We saw particularly strong and broad based pharmaceutical demand this quarter across brand, specialty, consumer health and our generics program. We are pleased to again support our customers with commercial distribution of the COVID 19 vaccines and preparation for the fall immunization season.

And as I alluded to, the team executed our customer transition plans with urgency, realigning operational processes to address inefficiencies, facilitate the ongoing growth of the business, and support new customer implementations.

In GMPD while the Q1 financial results were below our expectations due to some unanticipated health and welfare costs that Aaron will cover in detail, our team continues to make progress against the GMPD Improvement Plan, which is unchanged, and take actions to enhance our supply chain resiliency.

We're confident in our plans to accelerate the performance of the GMPD business over the next two years while also continuing our near term value creation focus, as we outlined last quarter. Across our other businesses, Nuclear, at-Home and OptiFreight, we continue to be encouraged by the strong demand and underlying performance we are seeing as these businesses continue to expand and benefit from positive industry trends.

In summary, we're pleased to be in a position to raise our enterprise guidance for fiscal 2025 after the first quarter. Our business is strong and we're confident as we look ahead.

With that, let me turn it over to Aaron to review our results and updated guidance in more detail.

Aaron E. Alt

Chief Financial Officer, Cardinal Health, Inc.

Thanks, Jason, and good morning. Q1 delivered an excellent start to Cardinal Health's fiscal 2025, with outstanding results from the Pharma segment accompanied by solid operational performance from GMPD and the businesses included in other. As an enterprise, we grew operating earnings by 12% and EPS by 9% despite the recent customer transition. At the same time, the team adeptly managed through an anticipated negative working capital unwind overdelivering on our Q1 cash flow expectations and enabling us to continue to both invest in the business and execute on an early accelerated share repurchase program.

With the solid start to the year, I am delighted to share the headline that we are raising our EPS guidance to an EPS range of $7.75 to $7.90, and raising our adjusted free cash flow outlook for fiscal 2025 to a range of $1 billion to $1.5 billion. More on that shortly.

Let's review the results, starting with slide four. Total company revenue decreased 4% to $52 billion, better than we expected. Adjusting for the customer transition, total company revenue increased 15% versus the prior year, reflecting our strong organic revenue growth across the rest of our business. We also started to successfully onboard the first of the new customers that make up the over $10 billion of incremental revenue in Pharma that we've referenced in our guidance for the year.

Total company gross margin increased 9%, driven by positive trends in both brands and generics in the Pharma segment. While we tightly controlled discretionary spending during the quarter, on the face of our financials, SG&A grew by $91 million, or 8% versus prior year. Approximately half of this increase was driven by incremental health and welfare employee costs. This included substantially higher employee plan utilization costs. Both numbers of claims and cost per claim, as well as a one time catch up charge resulting from our third party actuary on whom we rely. Notifying us of a mistake in the calculation of our health and welfare plan liabilities from prior years. Even with that impact, we delivered operating earnings of $625 million, 12% higher than last year.

Moving below the line, interest and other increased $15 million to $27 million, primarily driven by lower interest income due to the anticipated lower cash balances. Our first quarter effective tax rate finished at 23%, up two percentage points due to the non-repetition of some positive discrete items in the prior year. As a result of our share repurchases, Q1 average diluted shares outstanding were 245 million, 2% lower than a year ago. The net result for Q1 was EPS of $1.88, growth of 9%.

Now turning to the segments, beginning with Pharma and Specialty Solutions on slide five. First quarter revenue decreased 5% to $48 billion due to the impact of the customer transition. Excluding that, revenue increased 16%, driven by brand and specialty pharmaceutical sales growth from existing customers. This included five percentage points of revenue growth from GLP-1 sales.

During Q1, we saw strong pharmaceutical demand across product categories, brand, specialty, consumer health and generics, and from our largest customers. Segment profit increased 16% to $530 million in the first quarter, driven by a higher contribution from brand and specialty products, including a favorable impact from the earlier seasonal launch of COVID 19 vaccine distribution and positive generics program performance. This more than offset the profit impact from the customer transition.

In specialty we saw strong, broad based performance across specialty distribution and biopharma solutions. Notably, specialty networks contributed to this performance as expected, and we are pleased with the progress on the integration. With COVID 19 vaccines, recall last year, the FDA's original approval for commercial distribution came on September 11th, and our demand peaked in October. This year, we've seen distribution peak within the first quarter. While the demand for COVID 19 vaccines in the second quarter is difficult to predict, trends tell us that we should continue to expect a modest headwind for the full year, with the tailwind we saw in Q1 more than offset by lower year over year COVID 19 vaccine sales in Q2. This overall impact is consistent with our prior guidance for the year. Our generics program continued to see volume growth coupled with consistent market dynamics, including strong performance from Red Oak.

We also need to give our team significant credit for planning ahead and executing quickly on our plans to optimize our cost structure and operations following the customer transition. We found incremental opportunities to improve our overall business as a result of the flexibility created by the contract transition. So overall, we are very proud of the pharma team navigating a large, complex change to the business while delivering a tremendous quarter of 16% segment profit growth in Pharmaceutical and Specialty Solutions.

Turning to the GMPD segment on slide six, revenue increased 3% in Q1 to $3.1 billion, driven by volume growth from existing customers. The solid operational progress made in the quarter was obscured by a $17 million year over year increase in the previously mentioned health and welfare costs, and resulted in GMPD segment profit decreasing to $8 million in Q1. As previewed last quarter, our results were also impacted by increased manufacturing costs, including some startup costs related to expanding domestic manufacturing to enhance our supply chain resiliency, which we expect to also impact Q2.

On the positive, an improvement in net inflationary impacts, including our mitigation initiatives and growth from existing customers, mostly offset the decline in the quarter. And we also again saw year over year growth in Cardinal brand volumes during the quarter. Finishing with the businesses reported in other, as seen on slide seven. First quarter revenue increased 13% to $1.2 billion due to growth across all three businesses at-Home Solutions, Nuclear and Precision Health Solutions and OptiFreight Logistics.

I'm pleased with the underlying performance of all three of our businesses in other, as they collectively grew segment profit in the quarter by 8%, driven by the performance of OptiFreight Logistics. OptiFreight had another strong quarter as demand for healthcare logistics technology and services continues to grow.

Now turning to the balance sheet. We ended the quarter with a cash position of $2.9 billion, which includes $200 million earmarked for the November debt maturity, with an additional $200 million to be paid through the time deposits held in prepaid assets and other on the balance sheet.

Adjusted free cash flow was a use of $1.4 billion for the quarter, better than our expectations, and [ph] this guide (11:42) reflected the large contract unwind and the unfavorable quarter end day of week timing we previewed on our Q4 call. During the first quarter, we continued to deploy capital according to our disciplined capital allocation framework. We invested $90 million in CapEx back into the businesses to drive organic growth.

We returned approximately $500 million to shareholders through the share repurchase and dividends, including a $375 million accelerated share repo program. We continue to invest in specialty by reaching an agreement to acquire Integrated Oncology Network for $1.1 billion, a deal which is not yet closed. Jason will elaborate on that shortly.

Now for our updated fiscal 2025 guidance on slide nine. Beginning with the enterprise. After the strong start to the year, we are raising our fiscal 2025 EPS guidance to the range of $7.75 to $7.90, a $0.20 increase at the midpoint from our prior guidance of $7.55 to $7.70, primarily reflecting our improved Pharma segment profit expectations. We are raising our adjusted free cash flow guidance to a range of $1 billion to $1.5 billion. We are also adjusting our guidance for our individual segments, as seen on slide 10.

For Pharmaceutical and Specialty Solutions, we are improving our revenue outlook to a decline of 2% to 4%, reflecting the strong broad based pharmaceutical demand trends we've seen so far, including increased expectations for GLP-1 sales. Our full year COVID 19 vaccine expectations are unchanged. Normalizing for the customer transition, fiscal 2025 revenue growth at the midpoint would now be between 18% to 20%. Our expectations for incremental volume from new customers and customer expansions is generally unchanged from what we outlined a quarter ago, over $10 billion of revenue in fiscal 2025. For segment profit, following the strength of the first quarter, we are raising our Pharma segment profit guidance for the full year to 4% to 6% growth, which I'll note is consistent with our long term target despite the contract transition. In terms of Pharma segment profit cadence, given the earlier COVID 19 vaccine season, along with the contract expiration, we continue to expect Q2 segment profit to be slightly down year over year with growth resuming in our third and fourth quarters.

Turning to GMPD. We are updating our GMPD segment revenue outlook to 2% to 4% growth, to reflect the recent notification of lost lower margin VA government distribution contracts, which will partially offset some of the new distribution volume we are onboarding in fiscal 2025.

We do continue to expect 3% to 5% Cardinal Health brand revenue growth for the year. For segment profit, we are updating our fiscal 2025 guidance, primarily to reflect the impact from the health and welfare costs, I referenced. We are still in the fight to hit $175 million in segment profit for the year, and the GMPD team is executing on additional initiatives to recover the gap arising from Q1 results.

Nevertheless, given the unanticipated health and welfare impacts and other externalities impacting the business, we think it pragmatic in the near term to adjust our GMPD segment profit outlook to a range of $140 million to $175 million.

I want to emphasize that while the timing and impact of specific incremental actions identified by the team to support the GMPD strategy and profit growth may be pressed to fully impact our fiscal 2025, those efforts continue to support our focus on $300 million as our profit goal for fiscal 2026.

Regarding GMPD segment profit quarterly cadence, we continue to expect profit to be back half weighted with sequential improvements each quarter, driven by the ongoing commercial and operational improvements in the business as well as seasonality.

We continue to expect Q2 to be impacted by higher manufacturing costs, along with some carryover from the higher health and welfare plan utilization we saw in Q1. In other, we are reiterating our prior guidance of 10% to 12% revenue growth for the full year and approximately 10% segment profit growth.

One note on others cadence, we are expecting an industry wide raw material shortage of moly 99 to impact the Nuclear business volume and profitability in Q2. As a result, we expect Q2 segment profit growth for other to moderate to the low to mid single digits for the quarter.

However, we expect these volumes to generally return in subsequent quarters as delayed procedures are rescheduled. With those details on the table, let's return to the enterprise guidance for a second.

On the positive side, we have the combination of a raise to our Pharma full year guidance which is reflective of our anticipated offset in Q2 from the earlier COVID-19 contribution and anticipated efficiencies incorporated for the rest of the year. Those positive trends are partially offset by a wider full year profit range we are providing today on GMPD. The combination gets us to our $0.20 raise to guidance at the midpoint, following our first quarter.

Before I wrap-up, a couple of comments on capital deployment, our disciplined capital allocation strategy continues to be our North Star, invest in the business, protect our investment-grade credit rating, provide baseline return of capital and assess additional M&A and return of capital opportunities.

Of note, even with our announced investment and return of capital plans, we expect to be at the bottom end of our targeted leverage range of 2.5 times by the end of fiscal year 2025. As I hope you can tell from our fiscal year 2024 and Q1 fiscal 2025 announcements, our eyes remain firmly focused on delivering shareholder value creation over the long-term.

To close, we started fiscal 2025 strong. I am especially pleased to see the performance in our Pharma segment. Raising segment guidance in our largest and most significant business to our long-term target while managing through quite a large change is further proof of the strength and resilience of this business. Across all of our businesses, I'm excited for the value creation opportunities in front of us and look forward to updating you on that in coming months.

With that, I will turn it back over to Jason.

Jason M. Hollar

Chief Executive Officer & Director, Cardinal Health, Inc.

Thanks, Aaron. The strong first quarter results build upon the momentum we've established over the past couple of years by ruthlessly prioritizing simplification and core operational execution to serve our customers and their patients with essential products and industry-leading service.

They are also a testament to the actions we've taken to solidify our core foundation and increase our exposure to higher growth in higher-margin areas. In Pharma and Specialty Solutions, we've been consistently focused on execution in the core and expanding in specialty.

This quarter, we made further progress on both fronts. We delivered strong operational performance across our distribution network. During the quarter, we achieved multiyear highs in productivity and our service levels reached their highest level in over a year.

A key part of our ability to maximize service delivery for our customers is our generics program. Red Oak continues to effectively execute its dual mandate managing both cost and available supply, which supports the positive volume growth and performance that we've seen and continue to expect.

On the businesses commercial front, we've seen successful renewals and extensions of key customers and a couple of recent customer on-boardings that have gone smoothly due to our team's continual customer focus.

In Specialty, we've seen strong continued momentum, both downstream and upstream. We're thrilled to have reached an agreement to acquire Integrated Oncology Networks (sic) Network (19:30) as we announced in September.

Together, Cardinal Health and ION will continue to push forward in our joint mission to improve cancer care in underserved communities. We will drive innovation through the Navista and Specialty Networks platforms to offer community oncologists who seek to remain independent a suite of clinical and economic offerings to improve patient care and enhance practice performance.

Integrated Oncology Network adds immediate scale to our offering. Across its 10-state footprint, ION's more than 100 providers deliver broad-reaching care in medical and radiation oncology, urology, diagnostic testing and provide other ancillary services. It brings to Navista additional proven in-house MSL solutions such as revenue cycle management, payer relations and formulary management.

When combined with Navista's tech solutions, focused on supporting the clinical and operational needs of independent community oncologists and Specialty Networks' PPS Analytics platform, we can offer a powerful combination for independent physicians to lower costs, improve outcomes and drive success in value-based care.

While we are pleased with the suite of services and capabilities we're building, we will continue to invest organically and actively evaluate additional inorganic opportunities to further accelerate our growth strategies across the specialty therapeutic areas.

Upstream with manufacturers, our Biopharma Solutions and Advanced Therapy Solutions businesses continue to develop new offerings. For example, we launched our Advanced Therapy Connect provider ordering solution in the quarter. The streamlined provider portal enables treatment centers to access their contracted cell and gene therapy products in one place to ensure seamless patient care and efficient product availability.

Turning to GMPD where we're continuing to execute our GMPD Improvement Plan initiatives. Our team is operating with urgency, driving positive operational progress across key priorities, implementing significant distribution wins, taking actions to drive our Cardinal Health brand pipeline, strengthening our offerings and mitigating the impact of macro challenges, while enhancing our supply chain resiliency.

During the quarter, we secured key distribution renewals and remain on track to implement some notable new distribution wins during the year. Overall, utilization trends remained stable, and we're seeing consistent growth across our customer base.

With Cardinal Health brand, our leading indicators remain healthy. Service levels have continued to trend positively, back orders remain near multiyear lows, and we're maintaining industry-leading customer loyalty index scores for US distribution.

We're constantly striving to provide our customers and their patients with the right products at the right place and time. On that note, demand for the newest Kangaroo OMNI Enteral Feeding Pump has continued to build in fiscal 2025 with onboarding of thousands of patients in the US and Canada in Q1.

We look forward to expanding patient access to this pump globally throughout this fiscal year with launches into EMEA and APAC regions. Additionally, we are preparing to launch our next-generation Kendall compression device in the back half of the fiscal year.

The next-generation platform is designed for optimal outcomes to prevent deep vein thrombosis and pulmonary embolisms by enhancing blood circulation. We're also adapting our operations to the macro environment, while leveraging the diversity of our global supply chain.

During the quarter, we significantly expanded domestic syringe production at two US-based manufacturing facilities in response to industry-wide disruptions and tariffs. We're managing through external challenges such as the impacts of the East Coast port strike and southeastern hurricanes with minimal disruptions to our service. And as we've exited the quarter, we've seen a decline in international freight costs from the recently elevated levels.

We're continuing to take an aggressive approach to managing our cost structure and evaluating opportunities to accelerate planned initiatives in support of our goals. In short, with the significant progress we've achieved to-date, we remain confident in our turnaround plan and the opportunities for GMPD on the horizon.

Turning to our other businesses, in Nuclear and Precision Health Solutions, the business has continued its double-digit revenue growth with above-market growth in the core categories and Theranostics.

As Aaron indicated, we are anticipating that an industry-wide shortage will have an adverse impact on second quarter volumes for many of our core low energy products. We've been working closely with suppliers and maximize available doses to minimize disruptions as much as possible.

With PET, we're investing to increase our cyclotron capacity and geographic reach to meet increasing demand for diagnostic imaging agents such as GE Healthcare's Vizamyl used for early detection of Alzheimer's and dementia.

Outside the core, we've continued to see significant demand for theranostics products, which again grew revenue over 20% in Q1, most predominantly in the areas of oncology with products such as [ph] helix, IL-6. (24:40)

In at-Home Solutions, we're also continuing to see double-digit revenue growth and deliver a leading customer experience. We've seen strong growth across key categories such as CGM in urology, which supports our ongoing focus on driving positive operating leverage.

The benefits of our investments in additional distribution capacity and increased automation are beginning to take hold. In Q1, our primary operational metrics have achieved the highest levels on record for service, quality and efficiency. We expect to continue investing in the growth and capability of this business.

And in OptiFreight Logistics, we're continuing to invest in tech forward platforms such as our total view insights and evolve our capabilities to unlock [ph] precision-driving (25:22) insights and value for our customers.

For example, our recent product launches include enhancements to our limited liability shipment product, that provides coverage on critical shipments and makes it easier for customers to view spending trends and tracking on these shipments.

We're always working to add incremental value and capabilities to satisfy the needs of our customers. At an enterprise level, the actions we've taken to strengthen our balance sheet over the past several years, along with our team's relentless attention to optimizing our working capital has positioned us with significant financial flexibility.

We're continuing to invest in the business, return capital to shareholders and prioritize the right strategic choices to accelerate our long-term growth. We are in an active M&A environment, and we'll continue to pursue inorganic activity to those areas that fit with our strategic priorities of investing primarily in specialty as well as the other growth areas of at-Home, Nuclear and OptiFreight.

Before I wrap-up, I'd like to acknowledge all those affected by the devastating southeastern hurricanes. Our priority is always the wellbeing of our employees and our customers. I'm proud but not surprised at how the Cardinal team has navigated challenges to continue delivering for our customers and their patients.

To close, we had a great start to fiscal 2025 and are excited to continue building upon our momentum. Thank you to our team for their many tireless efforts fulfilling our role as health care's most trusted partner.

With that, we will take your questions.

QUESTION AND ANSWER SECTION

Operator: Thank you very much Mr. Hollar. [Operator Instructions] Today's first question will be coming from Lisa Gill calling from JPMorgan. Please go ahead.

Lisa C. Gill
Analyst, JPMorgan Securities LLC

Q

Hi, thanks very much and good morning. I just really want to focus on the drug distribution side of your business, which had really great results, just a few questions. First, when I think about the vaccine, thank you for calling out the revenue component, Jason or Aaron, can you talk the margin? Is that materially better? Or is there something else that was driving the margin improvement when we think about the quarter?

And then secondly, when you called out the revenue improvement around Specialty, what we've heard from some of the managed care companies is that changes in IRA is potentially driving incremental volumes, especially around specialty drugs. And those changes will increase as we think about calendar 2025. So I'm just curious as to how you're thinking about volumes there, margins there. So just overall, my two questions [ph] in (27:58) a single question would just really be around that segment. First being, how to think about the vaccine and contribution to the margin? And then secondly, how do we think about what's happening on the specialty side. Thanks so much.

Jason M. Hollar
Chief Executive Officer & Director, Cardinal Health, Inc.

A

Yes. Thanks, Lisa. And I'm glad you asked that question first because that's, I think, very much the highlight of this quarter is what's driving the Pharma segment. We gave a lot of color in the script, but let me go a little bit deeper and just put some additional commentary to behind it. It was a strong quarter for the Pharma segment, and you referenced a couple of the key components, and I'll get into those, but let me just kind of back up and talk about the key drivers overall because what you're going to hear from me is there's not any one thing in particular that drove the success this quarter. There were -- I'll bucket it into three key buckets. First of all, and I think it's the essence of your question is, we did see very strong and very broad demand utilization across various customers, across various products, classes of trade. Really, all corners of the Pharma business was strong from a utilization perspective.

Again, whether we're talking about brands or in consumer health or generics, you call out specialty, within specialty, we saw strength in distribution as well as biopharma services, solutions. And so we have across that spectrum, some really good strength. Specifically with COVID, yes, the volume was stronger this quarter because the FDA approval, of course, was about a month earlier than last year. So September 11 last year, middle to late August this year. So we had – the peak of COVID volumes clearly was in Q1 this year. It was clearly in October in Q2 of last year. So that is a difference.

However, I would highlight that the actual contribution to year-over-year earnings for the Pharma segment was a small tailwind, a slight tailwind associated with COVID. So higher and better than what we thought for the first quarter, but not a significant driver of those year-over-year results. It was the other breadth and depth of the strength of the utilization that was a bigger driver.

One last comment on the COVID vaccines as well, we see the timing difference for Q1 and Q2. For the full year, we still anticipate being the same – a modest headwind year-over-year, but that will be -- all that headwind will be in the second quarter. So that's the first point, the primary point, strong volume across the board. Second point is the volume that we did see, we did see some favorable mix. So the types of customers [ph] across the (30:36) trade was more favorable. But I would highlight that, that's really on the back of that broad strength in underlying utilization.

And then the final leg of the stool is the fact that with that volume, we had fantastic service levels, multiyear productivity enhancements. In a quarter in which we had a lot of change, a lot of transition of customers, we performed incredibly well, meaning that, that volume that we did have we're able to deliver it efficiently. And to some degree, we were able to actually even deliver it, right, having good service levels, improved service levels in this quarter, strong levels that allowed us to actually execute upon that. So those are the drivers. It's more than just vaccines, it's more than just specialty.

Within your question around IRA and perhaps there may be some dynamics there, we did see specialty growth faster than the overall, when we look at our overall enterprise growth, pharma growth ex the large customer transition that was 16%. When you look at specialty in the same way, it was a little bit higher than that. So we did see some strength there. But I wouldn't say that this was driven by that. It was a component of that underlying growth.

Matt Sims
Vice President-Investor Relations, Cardinal Health, Inc.

A

Next question, please.

Operator: Yes, sir. The next question will be coming from Michael Cherny of Leerink Partners. Please go ahead.

Michael Cherny
Analyst, Leerink Partners LLC

Q

Good morning. Thanks for taking the question. Maybe I'll try a similar approach to Lisa, one question but a couple of pieces tied into it. I just want to bridge the gap on the 300 basis point uptick in Pharma guidance for the year. Is there any way – I mean, Jason, I heard you talk a lot about utilization improvements. But any way you can give us a sense of what were the biggest drivers that led to the full year improvement? And specifically within there, you mentioned the COVID headwind being modest year-over-year. I just want to make sure it's the same level of modest, and then anything you can say on GLP-1 economics, whether that played any role in the guidance uptick or not? Thank you.

Aaron E. Alt
Chief Financial Officer, Cardinal Health, Inc.

A

Good morning. Happy to talk and provide some perspective on the updates to guidance for Pharma. And, of course, starting where Jason left off, we are really pleased with the Q1 performance, leading to the raise to our guide to actually to our long-term target of 4% to 6% in profit growth for the year. It's really driven by the strength and the resiliency of the business in Q1 that we see continuing as we carry forward.

Now part of this is just execution. You heard Jason reference the strong broad-based demand, right. That certainly assists in the raise to our guidance. It's also the case that as we walk into Q1, we were very focused on how are we going to execute as part of the customer transition. And the good news is, is that we managed – the team managed that very well, both from an income statement perspective and from a working capital perspective.

The impact that we were anticipating in Q1 was offset by significant simplification. We got more done there than we had anticipated. Specialty Networks contributed, the new customers. You heard me say we've started to onboard those as well. And so the pieces are really coming together, helping to give us more confidence than as we carry forward through the year as well, how the offset of that business will continue.

Now our guidance assumes consistent market dynamics in our generics portfolio. We saw strength in Q1 in generics, and we anticipate those consistent market dynamics are continuing. Our guidance also continues to see increased contributions from brand and specialty products. I won't repeat what Jason just had to say about that category.

COVID-19, we did guide at the start of the year. And indeed, our guidance continues that it will be a modest headwind for us through the year, notwithstanding, that it was a modest tailwind for us during Q1.

On the revenue side of the house, right, of course, we did call up our overall guide there. And that's driven in part by the strength from the existing customers and strength from the new customers, and GLP-1s are continuing to contribute and grow more so than we had originally expected, and that's about four percentage points of the revenue increase.

Now from a cadence perspective on the guide, anticipating perhaps your next question, Q2, we are guiding to be slightly down due to the headwind from COVID-19. The second half, we are expecting to be consistent with the guide of 4% to 6% that we have for the long-term. And as I frequently say, Q3 will be the highest dollar profit quarter just given that's when we see the impact of brand inflation over the course as well.

One final note on the guide. Our guide does not include the impact of ION, of the Integrated Oncology Network acquisition. We will provide that update to our guidance when we close, although I am pleased to report that, the

HSR waiting period on that transaction has now expired. And subject to the completion of some other customary closing conditions, we are anticipating that we're going to close that deal by the end of the calendar year.

Matt Sims A
Vice President-Investor Relations, Cardinal Health, Inc.

Next question, please.

Operator: Our next question is from Erin Wright of Morgan Stanley. Please go ahead.

Erin Wilson Wright Q
Analyst, Morgan Stanley & Co. LLC

Great. Thank you. Yes, Pharma was strong, but I do want to ask on medical here. So how do we think about the quarterly progression in medical at this point for the balance of the year? And then how are you thinking about kind of just underlying demand trends, excluding some of those dynamics that you were talking about in your prepared remarks, but just underlying utilization across that medical segment?

Aaron E. Alt A
Chief Financial Officer, Cardinal Health, Inc.

Appreciate the question. Let me offer some perspective on both the quarter and the year as we carry forward. I want to start with the headline that we are still in the fight to hit the $175 million that was our original guide for the year. And it is absolutely the case that we continue to make progress against the GMPD Improvement Plan and our fiscal 2016 target of $300 million, which is unchanged, notwithstanding the results in Q1. We did update our guide for the year to be $140 million to $175 million, primarily reflecting some unanticipated health and wellness costs.

And just a little bit more context on that. At the enterprise level, that was around $45 million. I think, I called out about half of the $91 million increase in overall SG&A. About a-third of that was an error by our actuaries tied to in prior years. The rest was tied to a notable increase in the number of claims as well as a notable increase in the cost per claim at an unusual level for us. That's really what was driving the Q1 performance. We are otherwise quite pleased with the GMPD progress against the plan. The tenacity they showed and continue to find additional opportunities to help drive the plan.

Now, the health and wellness challenges we aren't anticipating, they'll be the same level in Q1, certainly, given the breakdown I just gave you. They will modestly carry into Q2. But the team continues to accelerate as we knew they would, as we planned they would against the execution of the GMPD Improvement Plan for fiscal 2025. And we are seeing increased contributions from the plan initiatives. The mitigation of the supply chain cost inflation is well within progress, right? Significant year-over-year growth from the fiscal 2024 inflation mitigation that we've already experienced.

We are anticipating the Cardinal Health brand revenue growth, it will continue following the 3% fiscal 2024 revenue growth there. And the team has proven very tenacious in finding additional ways to simplify and cost optimize their business as we carry forward. From a cadence perspective, the cadence for our guide remains unchanged from our prior guidance. We've always said the plan – the GMPD Improvement Plan will be back half weighted and indeed, that continues. There's no change to the overall seasonality of the business from what we've described previously, but we are expecting sequential improvement quarter-over-quarter as we push ahead.

Jason M. Hollar
Chief Executive Officer & Director, Cardinal Health, Inc.

A

The only thing I would add is there's an element of utilization, I think, in your question, Erin. You certainly didn't see the same level of strength on the medical side that we have seen on pharma products, but with that said, it's fairly consistent utilization than what we've seen more recently, historically in the last year or two. So we're not seeing big changes there, which to me is partly positive just given when you think about all the macro factors and the hurricanes and, of course the disruptions with saline that we're not seeing big changes. Some smaller health systems we do see there being some deferral or cancellation of some procedures. But overall, we've not seen wide aspects throughout the industry on that. So cautiously optimistic that we as well as our customers are doing a fantastic job of managing through some disruptions, but at this point, we don't see materially impacting underlying utilization.

Matt Sims
Vice President-Investor Relations, Cardinal Health, Inc.

A

Next question please?

Operator: Yes, sir. Next question will be coming from Eric Percher of Nephron Research. Please go ahead. Your line is open.

Eric Percher
Analyst, Nephron Research LLC

Q

Thank you. A question on pharma. We heard some commentary from manufacturers of GLP-1s on inventory fluctuation. And I'd expect that the DSA agreements do not allow you to build inventory in pharma as pretty good visibility. So can we check that assumption? And then relative to GLP-1 inventory, have you been able to optimize as growth stabilizes? And was that at all a factor in improving cash flow?

Jason M. Hollar
Chief Executive Officer & Director, Cardinal Health, Inc.

A

Yes. So I'm aware of some comments on GLP-1 inventory. Obviously, I can't speak for the broader industry. For us, specifically, we manage this very closely. You can imagine that there's a lot of volatility in terms of strong demand, supply that does not meet that demand. So we're managing it at a very detailed manual level. And we have seen very static levels of inventory, relatively low levels of inventory that have not fluctuated much at all over the last several quarters. Relatively low levels of inventory, certainly, but it is our practice, our priority to get this product in the hands of our customers and ultimately to patients as quickly as possible. So no, we have not been changing our levels of inventory in any meaningful way whatsoever.

And as it relates to our impact on our underlying financials, it is 5% of that 16% Q1 revenue growth. So it was certainly meaningful to our top line and still that implies strong growth ex that GLP-1 impact. But as we've always said, it is not a meaningful driver of our earnings, and that continues to be the case and is not a significant driver of the financial results other than revenue for this particular quarter. And given the inventory is now fluctuating, it's also not a significant driver of our cash flow.

Matt Sims
Vice President-Investor Relations, Cardinal Health, Inc.

A

Next question please?

Operator: The next question will be coming from Allen Lutz of Bank of America. Please go ahead.

Allen Lutz
Analyst, BofA Securities, Inc.

Q

Good morning and thanks for taking the question. One for Aaron. The gross margin, really nice improvement year-over-year. Obviously, you're getting some type of benefit there from losing a low-margin customer. But is there any way to frame the puts and takes on the gross margin line, excluding that contract change? Thanks.

Jason M. Hollar
Chief Executive Officer & Director, Cardinal Health, Inc.

A

Actually, I'm going to take that one first. I know you give it to Aaron, I'll let him talk after me, but I'm the one that's made a lot of statements on this before Aaron arrived and after he arrived. So I did not – when gross margin rates were lower year-over-year, I always highlighted that's not how we manage our business. We manage our business on gross margin dollars. And so I'm not going to take credit for gross margin rate improvements when we lose a low-margin, large customer. So I appreciate the fact that we like the direction of those metrics. And all things being equal, I would love to have higher margin rates, especially if revenues are growing higher. But in a business like this that has negative working capital, very slim overall margins, what's important is how we manage the balance between our SG&A and our gross margin. And that's – this is another great example of it this quarter that regardless of the gross margin rate, we manage gross margin dollars higher than our SG&A increase, and that's what keeps this model working the way it is. And that's what we're going to continue be focused on. We'll celebrate the margin rate increases, which are largely driven by the cost reductions and the mix benefits and having more higher-margin customers, fewer lower-margin customers, but it's not a model change, and that's the key thing I want to get across. And I just realized I probably took all your talking points, Aaron, anything to add.

Aaron E. Alt
Chief Financial Officer, Cardinal Health, Inc.

A

I thought that was incredibly well said, Jason.

Matt Sims
Vice President-Investor Relations, Cardinal Health, Inc.

A

Next question, please.

Operator: We will now move to Kevin Caliendo of UBS. Please go ahead.

Kevin Caliendo
Analyst, UBS Securities LLC

Q

Thanks. Appreciate taking my question. So I just want to make sure there's been no necessarily any change in GLP-1 economics going forward at all. That's not driving in any way, the change in guidance for the full year. And two, sort of secondarily, one of the infusion companies who reported this week suggested that STELARA pricing, brand pricing was going to get come 1-1-2025 when biosimilars came. And I'm just wondering, I know part of that's infusion, part of that is subcu. But I'm wondering if a brand company lowers price to sort of a lower level, how does that impact you? Does this potentially impact you in any way? Can you just talk through the economics of how that would work and potentially impact you, if at all? Thanks.

Jason M. Hollar
Chief Executive Officer & Director, Cardinal Health, Inc.

A

Sure. Yeah. No, the GLP-1 economics, I think I basically answered that one before. So I don't think there's much else to add there. It's not a key part of the change. Again, I highlighted that broad strength, and I didn't even mention GLPs specifically when I was talking about the key drivers there. Again, we love innovation. We think that's great for the industry. It's great for us. It benefits – we like the volume. It helps, allow us to be even more efficient and things of that nature. But it's not something that specifically drove the underlying strength that we saw in all those other areas that I highlighted. So it's a component, but it's definitely not the driver.

In terms of the STELARA comment, this is not new when it comes to price changes that we see in our industry. The model continues to work in the way that makes sense for us. We basically operate on a fixed fee basis for our service. And that concept was recently tested yet again with insulin and those dramatic price reductions that we saw at that point and not only us, but our peers, you didn't hear us talking a lot about that type of flow through. So we continue to believe that we are, by far, the best alternative to delivering these products safely, securely and efficiently in the marketplace. And when the price levels change, the dollar fee we get for those prices from – to stock and support on the manufacturer side is unchanged. We provide the exact same service and expect to get the exact same financial compensation for that. So we continue to expect that model to continue to evolve. And whether you're talking about, again, insulin or STELARA, you also have all the IRA products that will happen in phases over – well, the future. In each of those cases, we would expect that model to continue to hold given how we have structured that today and how we'll continue to evolve with it.

Matt Sims
Vice President-Investor Relations, Cardinal Health, Inc.

A

Next question, please.

Operator: Our next question will be coming from Eric Coldwell of Baird. Please go ahead.

Eric White Coldwell
Analyst, Robert W. Baird & Co., Inc.

Q

Thanks very much. Good morning and congrats on the good performance here. I had a couple just quick ones on GMPD. I just want to confirm that profit in the segment would have more than doubled it looks like, if not for the unexpected increase in health and wellness costs? And just – so I guess a confirmation on that. And then is it possible to size the incremental manufacturing costs as you build out the syringe capacity in the US? And also talk about what you're seeing with international costs across other products.

We're hearing some suppliers might be raising their costs as we're seeing some of these China tariff knock-ons and then some of the other limitations to China product coming into the US market for other reasons. So I guess a multifold question around GMPD, but anything you could help us size what, if there is such a thing is underlying profit growth ex health and wellness and ex the increase in manufacturing costs would be helpful? Thanks.

Aaron E. Alt
Chief Financial Officer, Cardinal Health, Inc.

A

Appreciate the questions. A couple of quick responses. First, your math is no doubt correct where if you add the $17 million headwind from health and wellness to the $8 million delivery that would [indiscernible] (49:00) mid-20s profit delivery on an operating basis for the business ex that one adjustment. And then broadly, the quantification or the estimation, if you will, of the manufacturing costs it was a similar dollar impact to the health and wellness impact in Q1.

Jason M. Hollar
Chief Executive Officer & Director, Cardinal Health, Inc.

A

Yes. And on your last part of your question related to costs, you're referencing products coming out of China, you're really getting at the tariffs that are going to go into place here beginning in January and then rolling out later.

So we – let me make a broad statement about it that I think is consistent with how to think about it in the short-term. We have a very diversified supply base. But it's, given it's diversified, it's not entirely in the US. We've highlighted about half of our Cardinal Health brand products come from North America, which does include a decent amount coming out of Mexico as well.

But we use some degree out of China, less than 10% sourced out of China. We don't manufacture anything in China, but we use Southeast Asia, we use Latin America quite a bit as well. And like I mentioned, US and Mexico. So we have a very diverse supply base that has served us fairly well. We had challenges, of course, during COVID, when perhaps too much was in Asia, and we continue to migrate that.

But when you add tariffs on top of it that is something that will raise cost, there's no doubt about that. It will mean that we will take it from the economically optimal location to one that's less optimal. And that will raise costs not only for us, but throughout the industry. And you know our margins, you know the margins in this space that – if there's a 10% across-the-board type of tariff, that will have to flow through in some way.

We will do everything we can to keep that from flowing through entirely to our customers, but there will be some impacts that will have to be absorbed. So your commentary around some data points that we're already seeing it for these very short list of products, namely syringes and PPE that's occurring here in the near term, I think, is representative of that.

Those are products that are largely sourced out of Southeast Asia and especially into China, and you are seeing some pricing changes that are coming through the marketplace anecdotally, and we think that makes sense because the low-cost alternative is being impacted with a higher cost, and that will have to flow through the supply base. Of course, we're working on solutions to minimize that impact. But I think it's something that should be expected that there will be price increases.

Matt Sims
Vice President-Investor Relations, Cardinal Health, Inc.

A

Next question.

Operator: We'll now go to George Hill of Deutsche Bank. Please go ahead.

George Hill
Analyst, Deutsche Bank Securities, Inc.

Q

Yeah. Good morning guys. Thanks for taking the question. I hope you'll forgive the joke, which is I have just one question, but in 27 parts. But actually, a lot of the questions that I'm getting this morning from investors focus on the Pharma OP outperformance in the quarter. And Aaron, Jason, I was wondering if you guys would either just maybe attribute, kind of, vaccine versus [ph] sounds like (52:10) GLP-1s weren't much versus generics and other?

And you guys called out the generics program where we've seen kind of an increase in some generic drug pricing, and we've seen an increase in generic drug shortages, which we both tend to think of as being able to contribute to Pharma margins. So again, just like outperformance kind of vaccines versus other and would just kind of love to hear your commentary on what's happening in the generic drug market as it relates to pricing and shortages.

Jason M. Hollar A
Chief Executive Officer & Director, Cardinal Health, Inc.

Yeah. I can, kind of, force rank. I mean, what we put into our comments and what's in the presentation, you can see that our brand and specialty products together are the greatest drivers. Within that, both brand and specialty were good drivers.

Again, I'll say it again, the vaccines were a slight year-over-year increase. I think we quantified before last year that was about $25 million of profit in the quarter. It was a little bit higher than that, but it's not the driver of it. Generics was notable. It's not as large as brand and specialty, but it was also a driver of it. And that's why I answered the question the way I did is that we're seeing strength in utilization across the board, and we had strong operational and cost performance as well. That was a nice tailwind.

More simple operating environment, of course, this particular quarter, even though we had a lot of change. We managed through that very well. But that's the best I can do given – and again, you can do the math with the revenue growth highlights. It was pretty good revenue as well with 16% ex the customer transition, 5 percentage points of that being GLP-1s. So still quite strong kind of core revenue growth, which translates into all those categories I referenced.

Aaron E. Alt A
Chief Financial Officer, Cardinal Health, Inc.

So, one thing, I would add is we did – we, as we usually do, we called out the fact that generics program had consistent market dynamics, which you should really take as the sign that we saw good volumes there because there's nothing extraordinary happening on the [ph] bio (54:18) So we manage those two sides together.

George Hill Q
Analyst, Deutsche Bank Securities, Inc.

Exactly.

Matt Sims A
Vice President-Investor Relations, Cardinal Health, Inc.

Next question, please.

Operator: Next question will be coming from Stephanie Davis calling from Barclays. Please go ahead.

Stephanie July Davis Q
Analyst, Barclays Capital

Hey guys, congrats on the quarter, and thanks for taking my question. I've got one that kind of dovetails on what Eric asked. I was hoping to hear how you're thinking about the puts and takes of the potential election outcome. Since you could have some easing M&A risk for pharma, there's potential tariff risk in GMPD, kind of your broader thoughts there would be helpful. Thank you.

Jason M. Hollar
Chief Executive Officer & Director, Cardinal Health, Inc.

A

Sure. Well, I think, the first thing I would think about is the good news is, I think most people in DC believe that affordable access to health care is really important. And when you've heard me talk about any of these topics, I talk about, we love affordability, we love transparency, we love access because ultimately, that drives the utilization for the right products to solve those patients' needs, which has helped us be an even better provider to those that ultimately provide those services to the patients. So, I don't see that at the highest level, there is a difference in wanting what's best for the patient. Of course, there's different ways to get there. You've heard my commentary already today about tariffs being something that could impact how prices flow through to the industry, and we see that our customers are already under a lot of reimbursement pressure and that's something that's certainly top of mind for us.

But at the end of the day, there's a lot more not known about how would flow through and how medical and pharma products would be included that creates just some level of uncertainty with that. But ultimately, in doing what's best for the patient is something that I think will always be the North Star, and we feel that we're very well positioned to work with either party, whether we're talking about the President or either of the other elements of Congress. So we're in a good spot, and we have a lot of momentum going into that, and we don't foresee that changing in the near, medium or long term.

Matt Sims
Vice President-Investor Relations, Cardinal Health, Inc.

A

Next question please?

Operator: We'll now go to Elizabeth Anderson of Evercore ISI. Please go ahead, ma'am.

Elizabeth Anderson
Analyst, Evercore ISI

Q

Hey guys. Thanks so much for the question. Can you talk about some of the simplification efforts? I think – I mean, obviously, this has been a longer-term trend for you guys. Where are we in that? How much of it was obviously driven by the contract change this quarter. But as we think about sort of the rest of the year and beyond, help us maybe think through that a little bit more. And then just one follow-up on the nuclear supply shortage timeline, like how do you see that evolving across the rest of the year in terms of like the potential timeline for that, if any kind of parameters you could help put on that would be helpful. Thank you.

Jason M. Hollar
Chief Executive Officer & Director, Cardinal Health, Inc.

A

Yes. Thanks. As it relates to simplification, it's not any one particular business. This is very much a core part of our broader strategy. It has absolutely served us well. And it's a bit cliché, but it is absolutely a journey and not a destination. So I think that there's probably more opportunity relative to the size of the business for GMPD than there is for Pharma. But even within Pharma, this quarter, I think, highlighted that we can do some things. I'm not sure we fully understood. So there's going to be an ongoing journey here to continue to challenge ourselves and continue to find additional ways to be even more efficient.

Throughout our whole enterprise, we don't use a ton of automation in all aspects of our business. We are absolutely testing and learning in different parts of the company that as we learn from that, we introduce it in other parts. So I think there's a lot of opportunity there. Within GMPD, whether we're talking about our distribution

network or manufacturing, manufacturing, especially is always an area that's always going to have opportunity through automation, through new and improved processes.

And one little anecdote with this, it shows up in the financial numbers, all the efficiencies. We have had this last quarter, fantastic safety metric, something we don't often talk about because it's not directly related to financials, but it's really important to our team. And it just shows that our underlying processes are working incredibly well, much, much better than we have historically, which is driving improvements throughout the process.

We've talked quite a bit about the investments we're making in at-Home. I referenced in some of my comments that we have best on record metrics this quarter all the way from quality to service, to efficiency, to safety was also an all-time high on record for that business as well, highlighting that the right investments where we're making more automation investments there than we are in other businesses as a percentage of the size of the business. And we're going to continue to learn from that and roll it out more broadly.

So we have received a lot of value from it. I think there's still more to come. But I would also say that's part of that continued ongoing expectation for those long-term targets that we have.

We have these types of cost reductions baked into that. And of course, our customers are always, wanting to share in that. And so we'll continue to find ways to be competitive, but also try to put some of that to the bottom-line as well.

On nuclear, so this is a bit of unfortunate timing with three of the six reactors that typically we derive our product from out of Europe for moly-99 being down simultaneously, some planned, some unplanned type of downtime.

The good news is we do have a pretty good line of sight as to those reactors coming back up in the next week or two. So this seems be about a 1-month type of impact for us, pretty significant for this month of October, starting to come up over the course of the next couple of weeks. And we have a pretty good line of sight to indicate that it will be resolved within this quarter then the volumes will take a couple more quarters. We believe most of that will come back because, of course, the [ph] then this (01:00:31) process is a patient that needs these types of scans. This is the low energy product that's usually more for cardiac type of scanning procedures. So these are patients that we expect to reschedule this in the next couple of quarters. But I doubt it will go beyond the fiscal year, but it's still a bit early to understand the full implications of that.

Aaron E. Alt A
Chief Financial Officer, Cardinal Health, Inc.

Just to put a pin on that, we have not changed our guidance for the full year for the other segments as a result of it. This was a timing or cadence observation only.

Matt Sims A
Vice President-Investor Relations, Cardinal Health, Inc.

Next question, please.

Operator: Yes sir. Next question is from Daniel Grosslight calling from Citi. Please go ahead.

Daniel Grosslight Q
Analyst, Citigroup Global Markets, Inc.

Hey guys. Thanks for taking the question, and congrats on the quarter. Just a question on GMPD and really, you mentioned the loss of a couple of regions in the VA program. I was curious if more broadly speaking you're seeing an increase in the competitive intensity within this segment, specifically as one of your competitors is rumored to be going public soon. Thanks.

Jason M. Hollar A
Chief Executive Officer & Director, Cardinal Health, Inc.

Yeah. My commentary will be the same as they've been in the past. It's a competitive and stable environment. That VA business you're talking about was relatively low margin, quite low Cardinal brand products attached to it.

So it's something that we would have liked to have kept it, but at the same time, there's not as much value associated with that as with other customers. So I don't see that, that's anything different than what we see within this space, just normal type of customer rotation.

Matt Sims A
Vice President-Investor Relations, Cardinal Health, Inc.

Next question, please.

Operator: Yes sir. The next question will be coming from Charles Rhyee of TD Cowen. Please go ahead sir.

Charles Rhyee Q
Analyst, TD Cowen

Hi, yeah. Thanks for squeezing me in here. Just maybe a couple of quick clarifications, Jason, you kind of made a comment, I think, maybe is related to hurricanes about some deferrals and cancellations of procedures. Are you saying just those are just hurricane-related and has distribution kind of, everything kind of picked back up since? And then also related to the healthcare higher utilization costs, is that – what are your assumptions for the level of utilization going forward? And is that already embedded into the guide? Thanks.

Jason M. Hollar A
Chief Executive Officer & Director, Cardinal Health, Inc.

Yeah. So to be clear, when I was talking about the hurricane that was, it was GMPD. And what I indicated was we're not seeing anything meaningful at all for that, that's both us, and our customers are managing it quite well.

Utilization is – what I was highlighting is that utilization is not as strong as on the pharma side, but I wouldn't say that's because GMPD is weak. I would just say that because pharma has been stronger, which I think leads into the second part of your question, which is that we're guiding for a normal utilization type of environment. So it would be more consistent with, as you heard from Aaron, our long-term guidance. That's basically effectively what – when you normalize for the COVID timing and things of that nature, what we're guiding for in Q2 to Q4 is much more normalized type of earnings growth, which would be consistent with the normalized level of utilization.

Matt Sims A
Vice President-Investor Relations, Cardinal Health, Inc.

Next question, please.

Operator: Thank you, sir. Our last question today will be coming from Stephen Baxter calling from Wells Fargo. Please go ahead. Sir, your line is open.

Stephen Baxter
Analyst, Wells Fargo Securities LLC

Q

Hi, thanks. Just one last kind of cleanup one on the Pharma guidance. So I appreciate all the comments that the strength is broad based and there's some differences in cadence to keep in here. I guess when we think about the $16 million raise on the EBIT line, you're very clear that it's not driven by COVID. Do we think about this as largely just being the Q1 underlying favorability in the business? Or should we think about this as the annualization of the favorability that we saw in the first quarter, seeing that strength is largely going to continue into in the balance of the year. Thanks.

Jason M. Hollar
Chief Executive Officer & Director, Cardinal Health, Inc.

A

Yes. So it depends on which pieces we're talking about. For the three elements that I talked about in terms of what's driving the growth of the business, the first element I highlighted was the underlying broad volume growth. And I'd highlight that would be for our Q2 to Q4 would be more normalized levels of growth. I also highlighted part of this quarter's favorability was favorable mix, that some quarters that's positive, some is negative, some is neutral, this particular quarter, it was more favorable. So that's the type of thing that normally does not continue in one direction or the other. And then, of course, our ongoing cost reductions is the smaller of the pieces, but still relevant in all this. So it's the combination of all that. But again, our guidance here anticipates a more normalized level, except for that COVID piece will certainly with pretty high confidence, we've seen COVID vaccines peak and come down now. We track this very, very tightly. It will be quite a modest impact headwind in the second quarter that's baked into this. But ex-that, we expect more normalized levels of performance.

Stephen Baxter
Analyst, Wells Fargo Securities LLC

Q

Great.

Operator: Thank you very much. As there are no further questions. Mr. Hollar, I'd like to turn the call back over to you for any additional or closing remarks. Thank you.

Jason M. Hollar
Chief Executive Officer & Director, Cardinal Health, Inc.

Yes. Just thanks again for joining us this morning. Again, an excellent start to the year showing our broad strength, resiliency and momentum of our broad business, especially our largest, most significant pharma business. We're pleased to be in a position to raise our guidance after only the first quarter and looking forward to continuing to give you more updates throughout the year.

With that, thank you, and have a great day. .

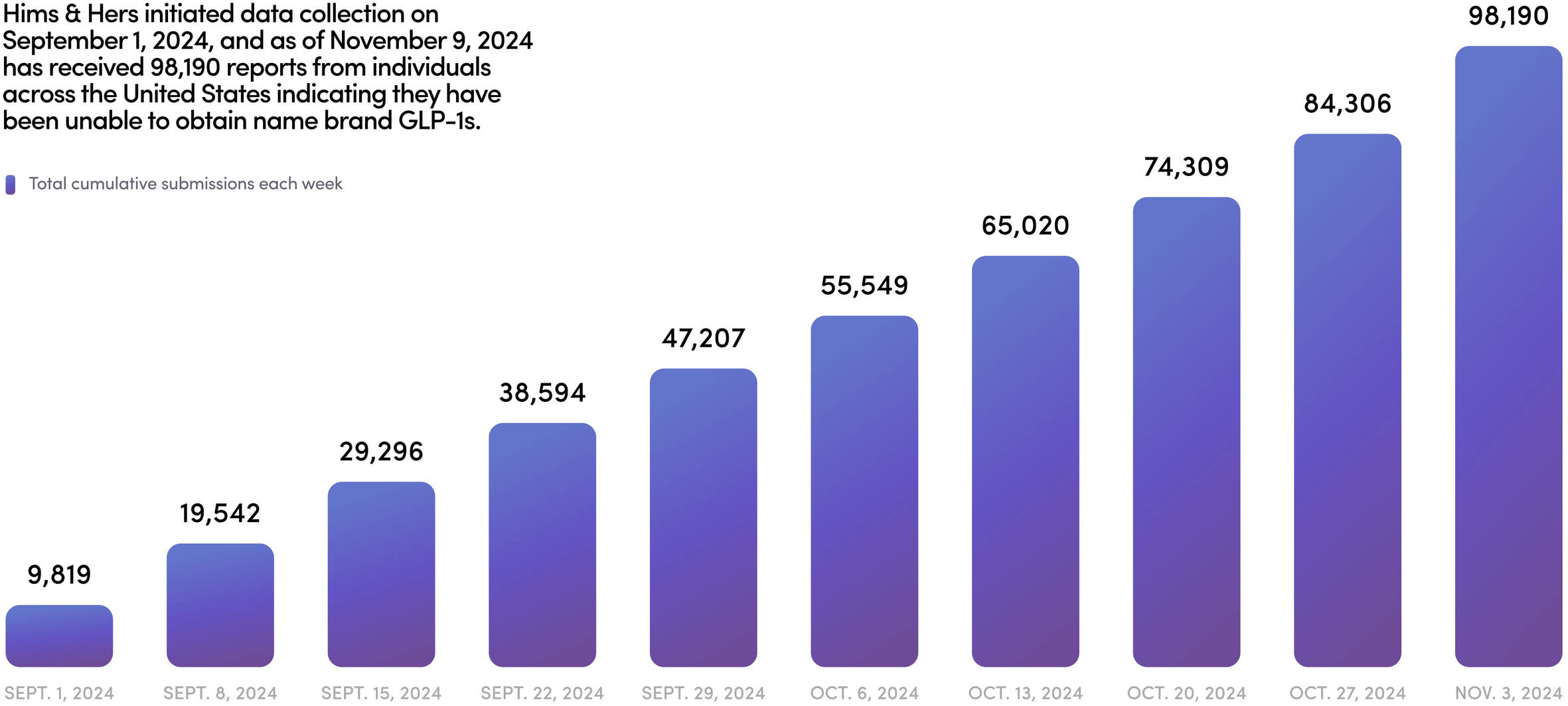
Operator: Thank you. That will conclude today's conference. Thank for your attendance. We wish you have a very good day. Have a good day, and goodbye.

Exhibit 7


hims & hers

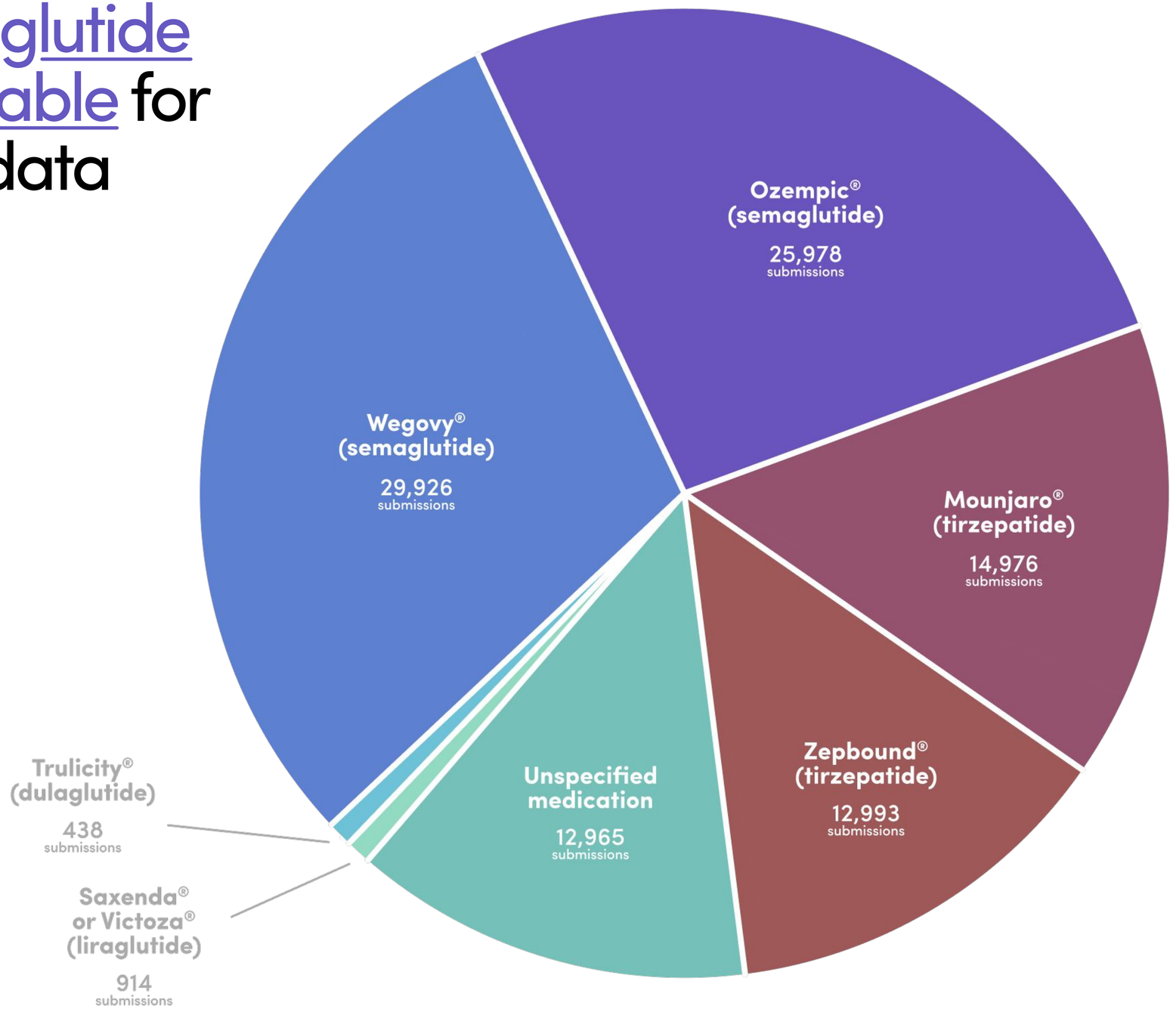
Over 98,000 people have reported an inability to access name brand GLP-1s

Hims & Hers initiated data collection on September 1, 2024, and as of November 9, 2024 has received 98,190 reports from individuals across the United States indicating they have been unable to obtain name brand GLP-1s.



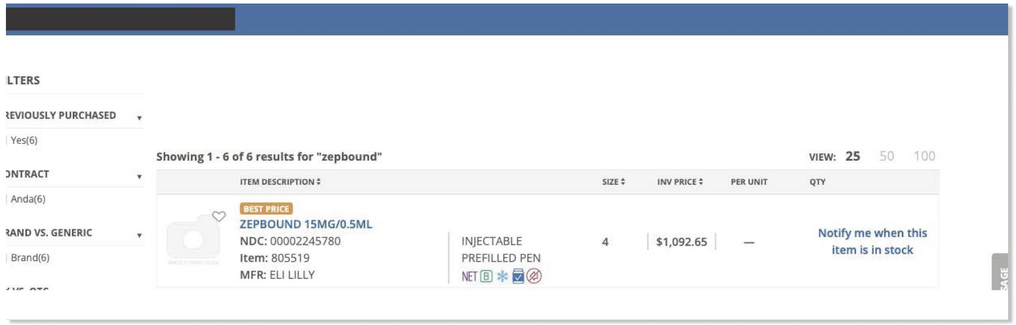
hims & hers

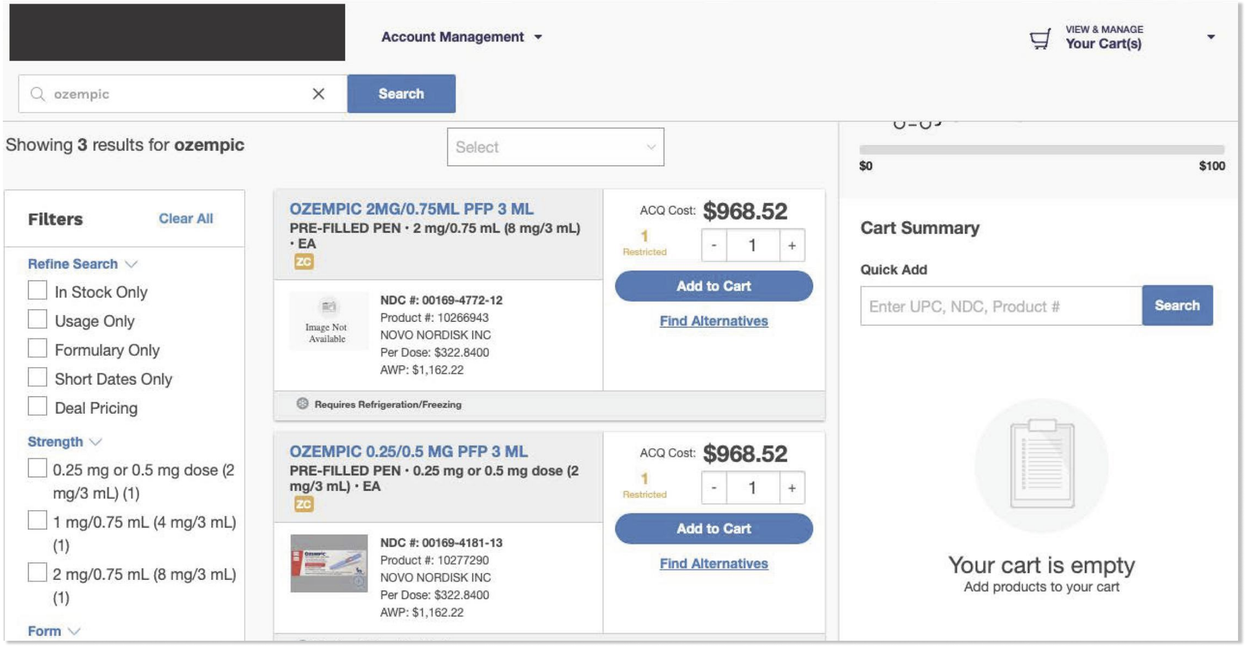
Tirzepatide and semaglutide remain widely unavailable for consumers reporting data through our platform

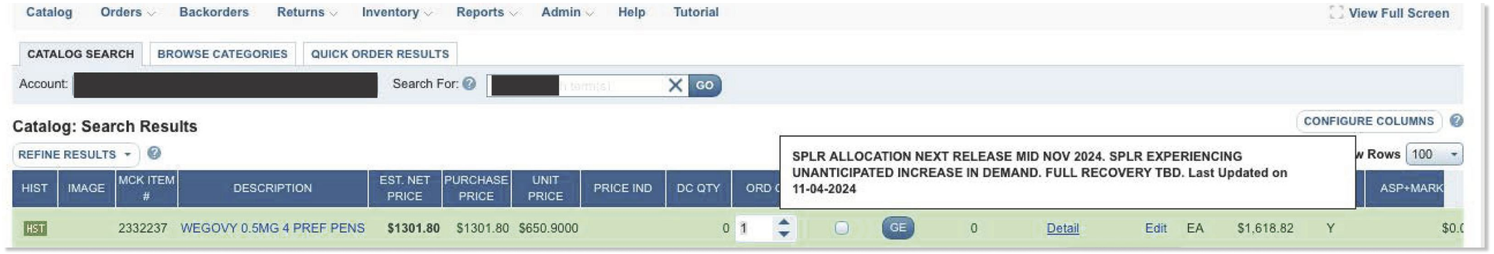


hims & hers

Our affiliated pharmacies continue to struggle to source branded GLP-1s across our leading wholesale partners







Supplier data as of 11/12/2024

hims & hers

Exhibit 8

11/12/2024

Dr. Adam Ripley
Asheville NC 28803
adam@dradamripley.com

Division of Drug Information (DDI)
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Docket No. FDA-2015-N-0030

Dear FDA,

I have been the owner or director of multiple compounding pharmacies in North Carolina and the State of Washington all dedicated to serving patients' needs with high-quality compounded medications. Lately, that has included GLP-1 treatments such as tirzepatide and semaglutide injection, which we prepare in our sterile compounding lab.

Over the past several years we have worked with thousands of patients in restarting a healthy lifestyle and to lose weight. We have been inspected by multiple state boards of pharmacy and passed a very rigorous NABP VPP inspection for multistate licensure.

Considering the current, prolonged shortages of branded GLP-1 products from Eli Lilly and Novo Nordisk, compounded alternatives have become an essential option for patients unable to obtain the brand-name products. I work closely with those patients and know many of them on a first-name basis.

We urge the FDA to not grant Eli Lilly's and Novo Nordisk's recent requests to place tirzepatide and semaglutide API on the FDA's Demonstrably Difficult to Compound Lists for 503A pharmacies and 503B outsourcing facilities.

As a pharmacy, we have faced significant obstacles in trying to order sufficient quantities of the branded, FDA-approved GLP-1 products from our wholesalers. Due to persistent backorders and allocation restrictions, these medications are consistently either unavailable or limited in quantities that are far too low to meet our patients' needs. These limitations prevent us from providing the continuity of care our patients rely on, especially those whose health depends on uninterrupted GLP-1 therapy.

Compounding pharmacies like ours have been able to help bridge this gap, using our expertise to prepare compounded tirzepatide and semaglutide according to established standards. We order the active pharmaceutical ingredient (API), as required by law, from FDA-registered

wholesalers who source the API from FDA-registered manufacturers. The API comes with a certificate of analysis that validates it is what it says it is.

The process of compounding these medications is straightforward, with only a few necessary ingredients, and can typically be completed in a short time. Following USP guidelines and state laws, we perform tests of a sampling from each batch to verity sterility, ensure potency, check for endotoxins, and confirm other essential quality standards.

Claims that GLP-1 medications prepared by state-licensed pharmacies are inherently unsafe misrepresent the thorough, nationally recognized compliance standards to which these medications are prepared. Our pharmacy follows strict protocols to ensure that each compounded product meets high standards of consistency and quality. Plus, they are tested by a third-party lab to verify potency, BUD, and sterility. Based on a scan of FDA's FAERS Database, the adverse events reported for compounded versions of the drugs are remarkably similar to those reported for the FDA-approved versions. One argument I have also seen is the multidose vial argument by manufactures. One of these manufacturers, Eli Lilly, has been putting insulin in multidose vials for decades. There are FAR more life threating issues that a patient could have if they overdosed on insulin by mistake, death being the most unfortunate. To say compounding into vials poses an unacceptable risk to patients is again a ridiculous statement and flies in the face of decades of their own packing options. A pen device may be more convenient for some but to say it's the only way something should be package is absurd. Decades of safe life saving insulin therapy from vials proves this to be nonsense.

One might think that if the API used by state-licensed compounding pharmacies was indeed demonstrably difficult to compound and more inclined to result in patient adverse events, it would show in the numbers. It simply doesn't. These API along with others (hormone replacement therapies to name another gross overstep) that manufactures are attempting to squash compounding by hiding behind DDC is absurd and 100% transparent as self-serving.

Restricting access to compounded GLP-1 medications would further limit patients' treatment options, leaving many without effective care during this shortage. We urge that the FDA reject drugmakers self-serving request to place GLP-1 peptide drugs on the Demonstrably Difficult to Compound List. Compounded versions of these life-enhancing drugs have proven essential in supporting patient care in this period of severe shortage. Limiting or restricting our ability to meet patient need during shortage would only deepen the impact of the shortage on the many patients who rely on GLP-1 therapies. Moreover, given the relative ease of compounding these injectable products, the APIs absolutely do not and never will meet the criteria for being "demonstrably difficult to compound."

Thank you for considering this request.

Sincerely,
Dr. Adam Ripley, PharmD, RPH, FAAFMM

Exhibit 9

KFF Health News

Who Gets Obesity Drugs Covered by Insurance? In North Carolina, It Hel...

Who Gets Obesity Drugs Covered by Insurance? In North Carolina, It Helps If You're on Medicaid

By Melba Newsome
DECEMBER 2, 2024

Still life of the big three injectable prescription weight loss medicines. Ozempic, Victoza and Wegovy. (MICHAEL SILUK/UCG/UNIVERSAL IMAGES GROUP VIA GETTY IMAGES)

After losing and regaining the same 20-plus pounds more times than she could count, Anita Blanchard concluded that diets don't work.

NBC NEWS

This story also ran on NBC News. It can be republished for free.

So when the University of North Carolina-Charlotte professor learned that Ozempic — developed to treat Type 2 diabetes — helped people lose weight and keep it off, Blanchard was determined to try it.

The state employee's health insurance initially covered the prescription with Blanchard kicking in a $25 copayment. Over the next seven months, she said, she lost 45 pounds and lowered her blood pressure and cholesterol. The most significant benefits, though, were psychological.

"It stopped the food noise in my head, relieved my anxiety, and I was no longer drinking like a fish," said Blanchard, now 60. "I'd have a glass of wine, and then that's it."

But North Carolina suffered from sticker shock as Blanchard shed pounds and thousands of others on the state insurance program — which covers more than 76,000 employees across 178 agencies, plus their dependents — tried to do the same. Ozempic and other glucagon-like peptide-1 (GPL-1) agonist medications accounted for 10% of the state employee health plan's annual prescription drug spending, according to a North Carolina State Health Plan fact sheet. The state treasurer projected the class of drugs would cost the state more than $170 million this year, with costs jumping to more than $1 billion over the next six years.

"This exceeds the amount the State Health Plan spends on cancer, rheumatoid arthritis, and chemotherapy medications," the State Health Plan said in a March statement.

The health plan's board of trustees eliminated coverage of this class of medications for weight loss starting in April. The plan continues to cover the drug for Type 2 diabetes management.

But in a twist this August, a separate part of North Carolina's government allowed the Medicaid program to start covering the drugs for weight loss — not just diabetes — for the state's poorest residents, who are disproportionately affected by obesity and related diseases. The state's Medicaid program covers more than 2 million people.

And now the outgoing Biden administration wants to follow suit, proposing on Nov. 26 for the federal government to cover the medications to treat obesity for Medicaid patients nationwide, in addition to Medicare patients.

Still, the North Carolina coverage change left state employees like Blanchard facing a stark choice — stop taking what she views as a miracle drug or pay as much as $1,200 out-of-pocket each month.

"They know diets don't work long-term for weight loss, yet they are denying coverage for a medication that has been effective," Blanchard said. "It's indicative of a profit-driven mindset that is more about cost savings than prioritizing patients' health."

The coverage switch highlights concerns about the cost of these medications and ongoing questions about who should get to have such drugs covered by insurance.

Several other states are also trying to reel in the expense of the medications. West Virginia canceled its pilot program to cover the drugs for its state employees. Connecticut state employees who are prescribed the drugs must participate in a clinical lifestyle management program.

The high prices have also raised concerns about the cost for taxpayer-funded health care programs, such as Medicare. The Centers for Medicare & Medicaid Services estimated that coverage under the Biden proposal would cost about $40 billion over 10 years, including an extra $3.8 billion for states. But the requirement wouldn't take effect until after President-elect Donald Trump takes office Jan. 20, giving his administration a chance to change it.

GLP-1 agonist medications, known by the brand names Ozempic, Trulicity, and Wegovy, have proved to be effective for weight loss as well as managing Type 2 diabetes. They work by triggering the pancreas to release insulin, slowing the rate at which the stomach empties, increasing satiety, and regulating

appetite by sending signals to the brain to tell the body it is satisfied. But patients typically need to stay on the medications to maintain their weight loss, meaning they face long-term costs.

In clinical trials, patients taking Ozempic also showed significant reductions in cardiovascular problems such as heart attacks and strokes, even those without diabetes, or before weight loss started, said Duke University cardiologist and researcher Nishant Shah.

Making these drugs available through Medicaid is in the state's long-term financial interest, said Kody Kinsley, secretary of the North Carolina Department of Health and Human Services, which doesn't oversee the state employee health plan. Unlike private or employer insurance plans, the Medicaid program receives generous rebates on these types of drugs, significantly reducing the cost, he said.

Calling North Carolina the buckle of the "Barbecue Belt," Kinsley noted that state's obesity rate exceeds the national average. The latest analysis from NORC research organization at the University of Chicago showed that 45% of adults in the state had a body mass index above 30, the threshold for clinical obesity, compared with 42% nationwide. That number was 55% for non-Hispanic Black adults in the state.

In addition, Kinsley said, with Medicaid the primary payer for long-term care, covering the drugs helps Medicaid's bottom line by reducing the need for nursing home care often driven by unmanaged chronic diseases.

"We're trying to put our dollars where they will lower costs in the long run," he said. "I spend almost a billion dollars a year on obesity-related diseases. If I can reduce that spend by even 1%, then these drugs are a no-brainer."

But what about people who aren't on Medicaid? Duke's Shah said the U.S. health care system needs to eliminate hurdles that make it difficult to obtain the drugs. Besides making the medication more affordable, he said, it should

encourage the use of weight loss drugs and treatment of obesity as a chronic disease instead of stigmatizing it as a moral failing.

"Whether it is drug cost, conditions that require the payer to approve them, the patient's health insurance plan, or the unaffordability of a plan that would cover weight loss, there are real-world barriers in our health care system," Shah said.

Family medicine physician Melissa Jones of Charlotte said she has often seen a bias against people in her weight management practice when they try to get these medications covered by private insurance.

"There's no shame in saying 'I have high blood pressure' or 'I inherited this condition from my family,'" Jones said. "But for some reason, there's shame associated with saying, 'I struggle with my weight.'"

Although Blanchard can't get her Ozempic covered anymore as a state employee, a concierge doctor gave her a prescription for a nonbrand version of the anti-obesity medications from a compounding pharmacy, available for now because of shortages of the brand-name versions. Though she believes it is less effective, she pays $225 a month for it.

"I can handle that," she said.

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Exhibit 10

NewsRoom

12/3/24 USA TODAY A1
2024 WLNR 23226003

USA Today (USA)

December 3, 2024

Section: News

Weight loss drug co-pays skyrocket for some patients

Prices, spotty insurance frustrating consumers

Ken Alltucker

December 3, 2024

"Is it more cost-affordable to be overweight and go to the doctor

and take medications for all

of the comorbidities that

come along with it?" Debbie Halstead

Cool Ridge, West Virginia

For Debbie Halstead, the weight loss medication Wegovy has been nothing short of a miracle.

The Cool Ridge, West Virginia, woman shed 60 pounds and lowered her blood pressure nearly 60 points. What's more, Novo Nordisk's blockbuster weight loss drug has relieved the "horrible arthritis in my knees" and made her feel "much, much better," she said.

But beginning Jan. 1, Halstead's federal Blue Cross Blue Shield health insurance plan is changing coverage for glucagon-like peptide 1 (GLP-1) drugs such as Wegovy and Ozempic. These drugs will be downgraded to a different coverage tier on her insurance plan.

The drug she now gets for $25 per month will skyrocket to $713 per month.

"Even if I didn't lose another pound, I'd take this drug as long as I could," Halstead said. "But at $700 a month, that's not going to happen."

Even as weight loss drugs such as Wegovy and Zepbound explode in popularity, many working-age Americans struggle to afford the medications. Some face escalating out-of-pocket costs with higher co-pays or other cost-shifting from their insurance plans.

Others are denied coverage, forcing them to pay out of pocket, scour for coupons, or secure the medication from compounding pharmacies that supply off-brand, discounted and potentially risky versions.

Only about one-third of those prescribed these drugs remain on them for a year or more, even though the medications are intended to be taken for life, like blood pressure drugs, and people who stop them typically regain many of their lost pounds.

For a class of medications that holds so much promise in a nation where 42% of adults are obese, consumers are frustrated that prices and spotty insurance coverage of GLP-1s have limited their access.

Certain Blue Cross Blue Shield plans have announced they won't cover the drugs for weight loss at all. States such as North Carolina no longer cover weight loss drugs for those on the state government's health insurance plan because of the high costs.

Those who purchase their own health insurance are unlikely to get coverage for anti-obesity drugs such as Wegovy and Saxenda. Just 1% of Affordable Care Act marketplace plans this year covered them, according to a June analysis by KFF, a nonprofit health policy organization.

Medicare, the federal health program for adults 65 and over, restricts coverage to those with diabetes or a heart condition.

Last Tuesday, the outgoing Biden administration unveiled a plan to extend obesity drug coverage to more than 7million Medicare and Medicaid enrollees beginning in 2026. But the rule would need to be finalized after President-elect Donald Trump takes office in January and it's not clear whether his administration will be willing to shoulder the roughly $40 billion price tag.

Insurance is 'biggest barrier'

Too many people struggle to afford the promising class of weight loss drugs due to insurance restrictions, said Dr. Angela Fitch, former president of the Obesity Medicine Association.

Insurance coverage for weight loss "is the biggest barrier we have in the United States because it is not a standard benefit," said Fitch, who is co-founder and Chief Medical Officer of knownwell, an obesity and primary care provider in the Boston and Dallas regions. Denying weight loss coverage "should be illegal, should be immoral and should be malpractice given the data we have today."

The high list prices and limited insurance coverage have frustrated consumers.

Halstead, who works at the Veterans Health Administration, received a letter from Blue Cross Blue Shield last month informing her of the price increase for her anti-obesity drugs beginning Jan. 1.

She searched for manufacturer's coupons to ease the financial crunch she'll face when the calendar flips to January. Wegovy's manufacturer, Novo Nordisk, offers a $225 coupon that would knock down her monthly cost to less than $500, which will still be difficult to afford.

Halstead has tried dieting and weight-loss surgery to shed pounds. None has worked as well as GLP-1 drugs, she said. She stopped taking cholesterol medication since losing so much weight and hopes to discontinue blood pressure-lowering drugs.

She questions whether insurance companies are short-sighted by scaling back coverage for weight loss drugs that could help millions improve overall health and eliminate the need for other maintenance drugs.

"Is it more cost-affordable to be overweight and go to the doctor and take medications for all of the comorbidities that come along with it?" Halstead asked. "Americans are caught in the middle of corporate greed and it is so sad and unfair."

In a statement, Blue Cross Blue Shield Association said the federal employee insurance program "regularly evaluates the usage and costs of prescription medications and makes changes to the list of covered drugs each year. As we have done for many years, we continue to have access to a range of covered weight loss prescription drugs."

Drugs costly to employers

Although many consumers face significant out-of-pocket costs, employers are trying to slow the drugs' runaway costs.

A survey by the benefits consultant Mercer cited the growing use of GLP-1 drugs as a reason prescription drug spending is the fastest growing part of employer health spending. In 2024, prescription drug spending increased 7.7%, slightly less than the 8.4% in 2023.

Nearly all health plans cover GLP-1 drugs for diabetes and a growing share of plans cover the drugs for obesity. In 2024, 44% of all large employers covered GLP-1 drugs for obesity, up from 41% last year, according to Mercer.

Just 5% of companies allowed workers to get GLP-1 weight loss drugs without restrictions, Mercer said. In addition to meeting BMI or weight-to-height ratio thresholds, most employers impose some conditions before employees can qualify for the drugs, such as obtaining authorization before filling a prescription or requiring workers to consult a dietitian, for example.

Companies want to limit the number of beneficiaries who might seek out weight loss drugs for cosmetic or nonmedical reasons.

"One way employers responded from last year to this year was to put some guardrails up," said Beth Umland, Mercer's research director of health and benefits.

The high list prices of these new weight loss drugs are costly for taxpayer-funded health programs. The Biden administration estimated adding anti-obesity drug coverage for Medicare and Medicaid enrollees in 2026 will cost about $40 billion over a decade. The high price tag prompted some lawmakers to call for more efforts to target the drugmakers' prices.

U.S. Rep. Lloyd Doggett, a Texas Democrat, urged the Biden administration to address "price gouging" from brand name GLP-1 drugs by authorizing generic competitors. The drugs are under patent protection. Wegovy's isn't set to expire until 2032 and Zepbound's in 2039.

Despite the patents, Doggett and other members of Congress have argued the federal government has the authority to authorize generic competitors in exchange for "reasonable compensation" to the brand-name manufacturers.

"Compelling Medicare and Medicaid to offer medications, whose prices they cannot now negotiate, will only bloat spending – costing taxpayers billions, raising premiums, and threatening the long-term security and promise of Medicare," Doggett said.

Consumers seek alternatives

Amanda Bonello, 35, knew she had to act when recent blood tests revealed her elevated blood sugar put her at risk for diabetes. The Marion, Iowa, mother of three worried about her family's history. Her mom has diabetes, and her dad has prediabetes.

Her doctor told Bonello that if she couldn't reduce her blood sugar, she would prescribe the diabetes drug metformin.

"I was looking for an alternative that would be better," Bonello said.

So she asked her doctor about the Eli Lilly drug tirzepatide, which is sold under the brand name Mounjaro to treat diabetes and Zepbound for weight loss.

Bonello's workplace insurance plan would not cover Mounjaro because she has prediabetes, not full-fledged diabetes. And the insurance plan didn't cover the weight loss drug Zepbound, which carries a list price of more than $1,000 for a one-month

supply. So she found a telehealth provider that could prescribe a less expensive version of the drug sourced from a compounding pharmacy.

She paid $211 out of pocket to get a month's supply of the weekly injections. She said she could not afford the brand-name drug without health insurance. Customers whose insurance doesn't cover Zepbound can purchase a one-month supply for $650, Eli Lilly said.

Bonello has been on the compounded version of the drug for one month and has lost 18 pounds. She estimates she'll need to lose about 50 more pounds to get down to her target weight.

"I feel absolutely incredible," said Bonello, who said she has more energy, takes frequent walks and keeps pace with her three sons, a 16-year-old and two 12-year olds.

But she's worried about continued access to the less expensive, compounded version of tirzepatide.

The Food and Drug Administration allows compounding pharmacies to sell copies of drugs when the medications are in short supply. Zepbound and Mounjaro have been in short supply since 2022, but the FDA declared on Oct. 2 the drugs were no longer in shortage. Compounding pharmacies face stiffer restrictions when a drug shortage is resolved. The FDA has also issued a warning against the use of these compounded drugs.

A trade association representing compounding pharmacies sued the FDA, and the agency agreed to reevaluate its decision to declare the shortage of the two drugs is over. In an Oct. 17 letter, the FDA told the Alliance for Pharmacy Compounding that it would not take any immediate enforcement action.

Still, the uncertainty worries consumers like Bonello who rely on these compounded drugs. In a Change.org petition signed by more than 7,000 people, Bonello and others asked the FDA to preserve access to compounded versions.

"If brand names are the only option, so many people will not be able to afford that, and it would just take hope and health away from so many people," Bonello said.

"Is it more cost-affordable to be overweight and go to the doctor

and take medications for all

of the comorbidities that

come along with it?" Debbie Halstead

Cool Ridge, West Virginia

---- Index References ----

Company: White River Junction VA Medical Center; Obesity Medicine Association.; NOVO NORDISK A/S; CHANGE.ORG, PBC; BLUE CROSS AND BLUE SHIELD ASSOCIATION

News Subject: (Health & Family (1HE30); Health & Wellness (1HE60); Obesity & Weight Control (1OB69))

Industry: (Financial Services (1FI37); Health Insurance (1HE18); Healthcare (1HE06); Insurance (1IN97); Pharmaceuticals (1PH33); Pharmaceuticals & Biotechnology (1PH13); Pharmaceuticals Cost-Benefits (1PH30))

Region: (Americas (1AM92); North America (1NO39); Texas (1TE14); U.S. Southeast Region (1SO88); U.S. Southwest Region (1SO89); USA (1US73); West Virginia (1WE81))

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End of Document

Exhibit 11

HEALTH AND SCIENCE

Prescription fills for weight loss drugs Zepbound and Wegovy more than doubled in 2024, GoodRx says

PUBLISHED THU, DEC 5 2024•9:00 AM EST


Annika Kim Constantino
@ANNIKAKIMC

KEY POINTS

Prescription fills for blockbuster weight loss medications in the U.S. more than doubled in 2024, even with limited insurance coverage and high out-of-pocket costs for the treatments.

That's according to new data from drug savings company GoodRx, which examined fill trends and spending patterns for weight loss drugs such as Novo Nordisk's Wegovy and Eli Lilly's Zepbound.

It offers more evidence of the insatiable demand for a buzzy class of medications called GLP-1 and GIP agonists, which have hefty list prices of roughly $1,000 per month before insurance or savings cards.

In this article

LLY -0.56 (-0.07%) GDRX UNCH

A combination image shows an injection pen of Zepbound, Eli Lilly's weight loss drug, and boxes of Wegovy, made by Novo Nordisk.
Reuters

Prescription fills for blockbuster weight loss drugs in the U.S. more than doubled in 2024, even with limited insurance coverage and high out-of-pocket costs for the treatments, according to data released Thursday by drug savings company GoodRx.

The figures offer more evidence of the insatiable demand for a buzzy class of medications called GLP-1 and GIP agonists, which mimic gut hormones to suppress appetite and regulate blood sugar. That includes Novo Nordisk 's weight loss drug Wegovy and Eli Lilly 's obesity treatment Zepbound, which have hefty list prices of roughly $1,000 per month before insurance or savings cards.

Prescription fills for Wegovy and Zepbound increased by more than 100% and 300%, respectively, since the start of 2024. Zepbound's jump reflects its first year on the market, as it was approved in the U.S. in November 2023. Wegovy won U.S. approval in 2021.

"It's just a pretty astronomical increase in sales, and because of that, a lot of eyes are on them around their affordability and accessibility," GoodRx director of research Tori Marsh said in an interview.

The data comes from GoodRx's new Weight Loss Medications Tracker, which examines fill trends and spending patterns in the U.S. for popular weight loss medications.

The high fill rates come even as just 9% of people with commercial insurance have unrestricted coverage of Zepbound, and 14% have unrestricted coverage of Wegovy, according to GoodRx. That refers to insurance coverage without any additional hoops for patients to jump through, such as prior authorization or higher BMI requirements.

Far higher rates of patients — around 60% to 70% — are under insurance plans with more restrictive coverage of the drugs. But Marsh said out-of-pocket costs can add up, even if a patient has insurance coverage for a weight loss treatment.

The average insured person taking Zepbound can expect to pay over $2,500 a year in copays for the drug, she said. GoodRx found that people spent $231 on average out of pocket for a monthly prescription of Zepbound from January 2023 to October this year.

"Insurance is just not the stopgap that it used to be," Marsh said.

Meanwhile, nearly 1 in 5 people with commercial insurance have no coverage of at least one branded GLP-1 and GIP agonist prescribed for weight loss.

GoodRx found that Americans have overspent by at least $200 million by paying the full retail prices for weight loss medications instead of leveraging savings options, such as GoodRx's coupons or assistance programs offered by Eli Lilly or Novo Nordisk. GoodRx said it calculated the overpayment number based on the average price people could have paid for a drug with a GoodRx discount.

GoodRx said people without insurance can save an average of $250 monthly, or $3,000 annually, using its coupons for weight loss drugs.

GoodRx's data is consistent with other research indicating spotty insurance for weight loss drugs in the U.S. For example, a survey published in October found that less than a fifth of large employers in the country include coverage of those treatments in their health insurance plans.

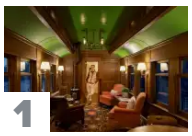
The federal Medicare plan also doesn't cover weight loss treatments unless they are approved and prescribed for another health condition. Research has shown that covering the drugs could significantly raise costs for employers and state and federal governments.

But the Biden administration in November proposed a rule that would allow Medicare and Medicaid to cover weight loss drugs for patients with obesity. If greenlit by the incoming Trump administration, the rule would significantly expand access to the treatments.

In this article

LLY -0.56 (-0.07%) GDRX UNCH

TRENDING NOW



1 **Family bought an abandoned train car for $3,000, turned it into an Airbnb that brings in over $90,000/year**

Exhibit 12

(/)

Express Scripts Pharmacy no longer taking new GLP-1 customers

NCPA **December 10, 2024**

ESI's home delivery pharmacy Express Scripts Pharmacy is no longer taking new GLP-1 patients, according to an updated FAQ on its website citing market demand. It's now directing customers who were recently prescribed a GLP-1 to their network retail pharmacies to get their prescriptions lled.

If even a big PBM like ESI can't afford to lose money on filling GLP-1 prescriptions, how is it realistic to expect that local businesses can? Independent community pharmacies are being asked to take on these patients and would be left underwater on those drugs because of insufficient reimbursement from PBMs like ESI.

You can read the updated FAQ here (https://www.express-scripts.com/frequently-asked-questions/does-express-scripts-pharmacy-dispense-glp-1-medications).

NCPA

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Exhibit 13

BREAKING NEWS

HEALTH AND SCIENCE

Ro to offer lower-price vials of weight loss drug Zepbound by teaming up with Eli Lilly

PUBLISHED WED, DEC 11 2024•8:01 AM EST UPDATED WED, DEC 11 2024•8:12 AM EST

Annika Kim Constantino
@ANNIKAKIMC

KEY POINTS

Direct-to-consumer health-care startup Ro said its platform will now offer more affordable single-dose vials of the weight loss drug Zepbound through a new partnership with Eli Lilly.

Ro will offer a “complete end-to-end” experience on a single platform and app, allowing eligible patients to receive a diagnosis and a prescription for Zepbound and have vials of the drug delivered to their homes.

That is made possible through a first-of-a-kind integration with Eli Lilly’s direct-to-consumer website, LillyDirect, and aims to streamline access to the popular treatment.

In this article

LLY +6.53 (+0.84%)

Patients will be able to access Zepbound single-dose vials at Ro

Health-care startup Ro on Wednesday said its platform will now offer more affordable single-dose vials of the weight loss drug Zepbound through a new partnership with Eli Lilly , which aims to streamline access to the popular treatment.

Ro said it will offer a "complete end-to-end" experience on a single platform and app, allowing eligible patients to receive a diagnosis and a prescription for Zepbound and have vials of the drug delivered to their homes. That is made possible through a first-of-a-kind integration with Eli Lilly's direct-to-consumer website, LillyDirect, which already offers home delivery of Zepbound vials through a third-party digital pharmacy, Gifthealth.

Gifthealth will dispense the vials to patients who receive Zepbound prescriptions through a provider affiliated with Ro.

Zepbound vials are a cash-pay product offered only through LillyDirect, meaning patients pay for it themselves with cash at a lower cost than the autoinjector form of the drug. The vials have the "most affordable" price of a branded GLP-1 drug before insurance, according to Ro. GLP-1s, a class of medications that mimic gut hormones to tamp down appetite and regulate blood sugar, have skyrocketed in demand over the last two years.

"Patients usually have to go to multiple places to get Lilly's drug, like the doctor's office then a pharmacy," Ro co-founder and CEO Zachariah Reitano told CNBC in an interview. "This integration really creates a seamless patient experience where they don't have to go anywhere else. They can access doctors, labs and a pharmacy that will give them access to Zepbound vials all in one place."

Ro runs a weight loss program that already prescribes Zepbound in a single-dose autoinjector pen, which patients can directly inject under their skin with the click of a button. But that form of the drug is far more expensive than vials, costing around $1,000 per month before insurance.

The 2.5-milligram and 5-milligram single-dose vials of Zepbound cost $399 per month and $549 per month before insurance, respectively, making them more accessible to those who don't have insurance coverage for the drug. Eli Lilly began offering those vials through LillyDirect in August.

"Whether you're covered by insurance, or whether you want the most affordable branded cash-pay GLP-1, which is the Zepbound vials, you can get all of those by coming to Ro," Reitano said, noting that the company will help eligible patients determine which form of the drug is best for them based on their insurance.

He acknowledged that roughly $400 to $500 per month for Zepbound is "still out of reach for many, but it is now far more in reach than" $1,000 or more.

Patients will be able to access Zepbound single-dose vials at Ro

Coutesy: Ro

The popularity of expensive treatments such as Zepbound and Novo Nordisk 's weight loss injection Wegovy has led to widespread shortages in the U.S. That issue has since subsided after Eli Lilly and Nordisk raced to ramp up manufacturing capacity for the drugs.

Still, cheaper compounded versions of GLP-1s have gained traction amid the limited supply of the branded medications. Eli Lilly is working to expand access to branded Zepbound in what appears to be a bid to crack down on compounded versions of the drug.

Patrik Jonsson, Eli Lilly's president of cardiometabolic health, said in a release on Tuesday that the goal of the new integration is to "break down barriers and provide patients with safe and effective options they can rely on."

The FDA is currently reconsidering its decision to take Zepbound off its drug shortages list following a lawsuit from a trade association representing compounding pharmacies. Removing Zepbound from that shortages list will essentially prevent compounding pharmacies from making custom versions of the drug.

If that ends up being the case, Reitano said Ro "will both follow all applicable laws and guidance" under the FDA and also "fight to make sure that our patients have access to the most effective products and most affordable products."

In this article

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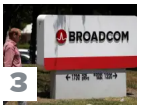
ealth Group CEO addresses Brian Thompson death, says health care system is 'flawed'

2



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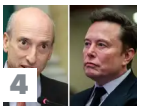
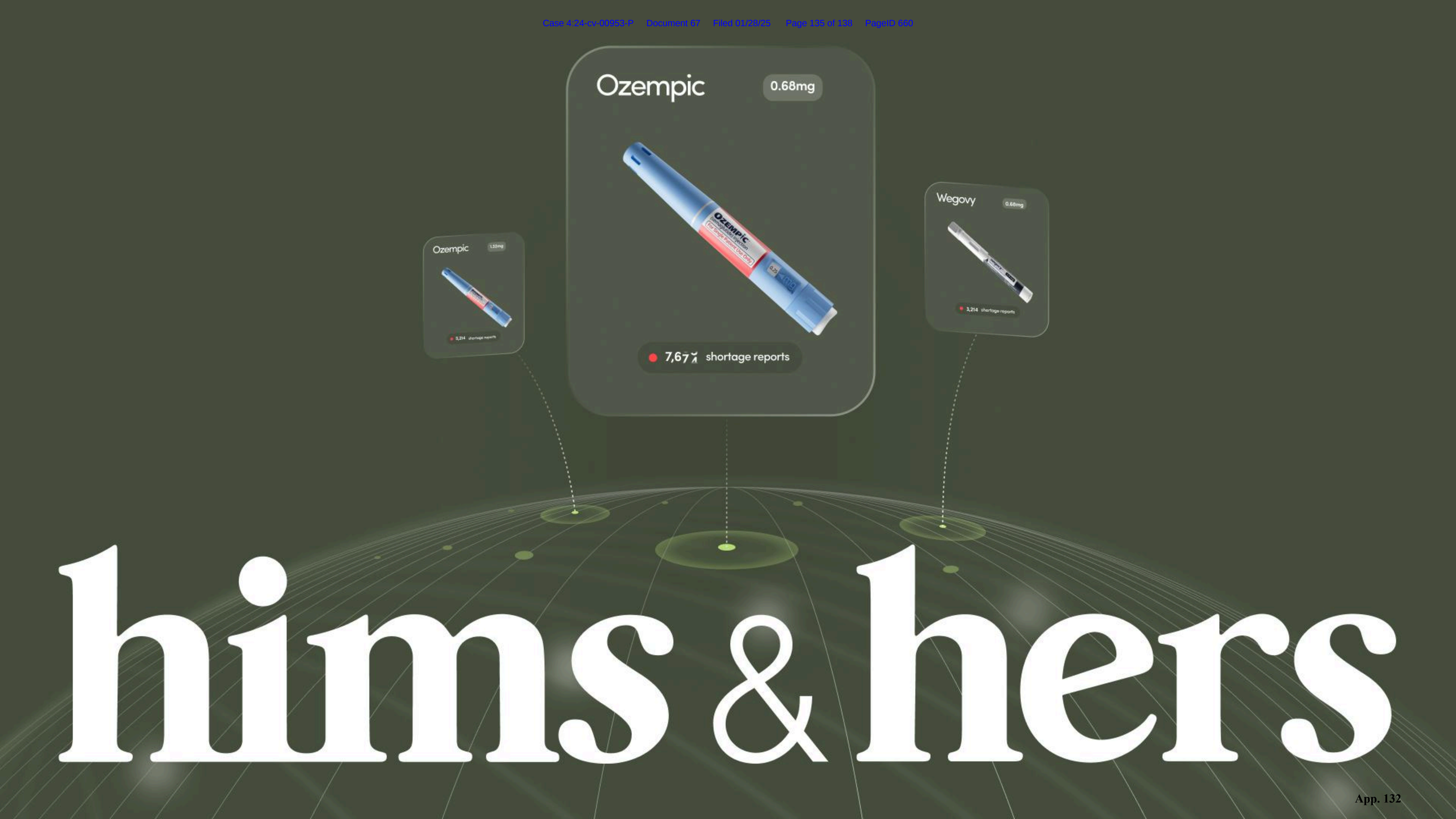

4 Elon Musk reveals SEC sent him 'settlement demand' after Twitter buyout probe

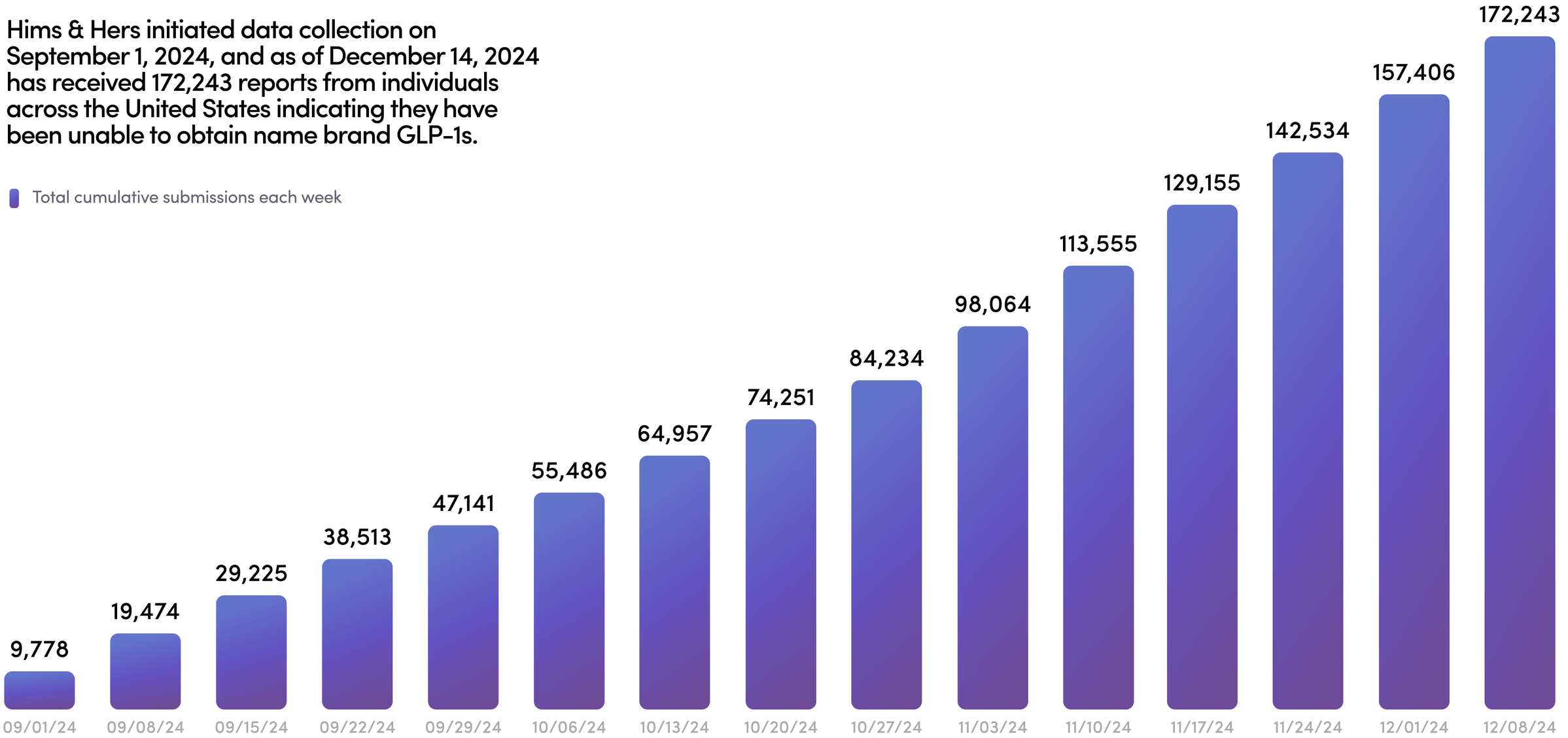
5 From Chili's to burger chains, here are the restaurant industry winners and losers in 2024

Exhibit 14


Ozempic
0.68mg
7,67
shortage reports
Ozempic
3,214
Wegovy
0.68mg
3,214
hims & hers

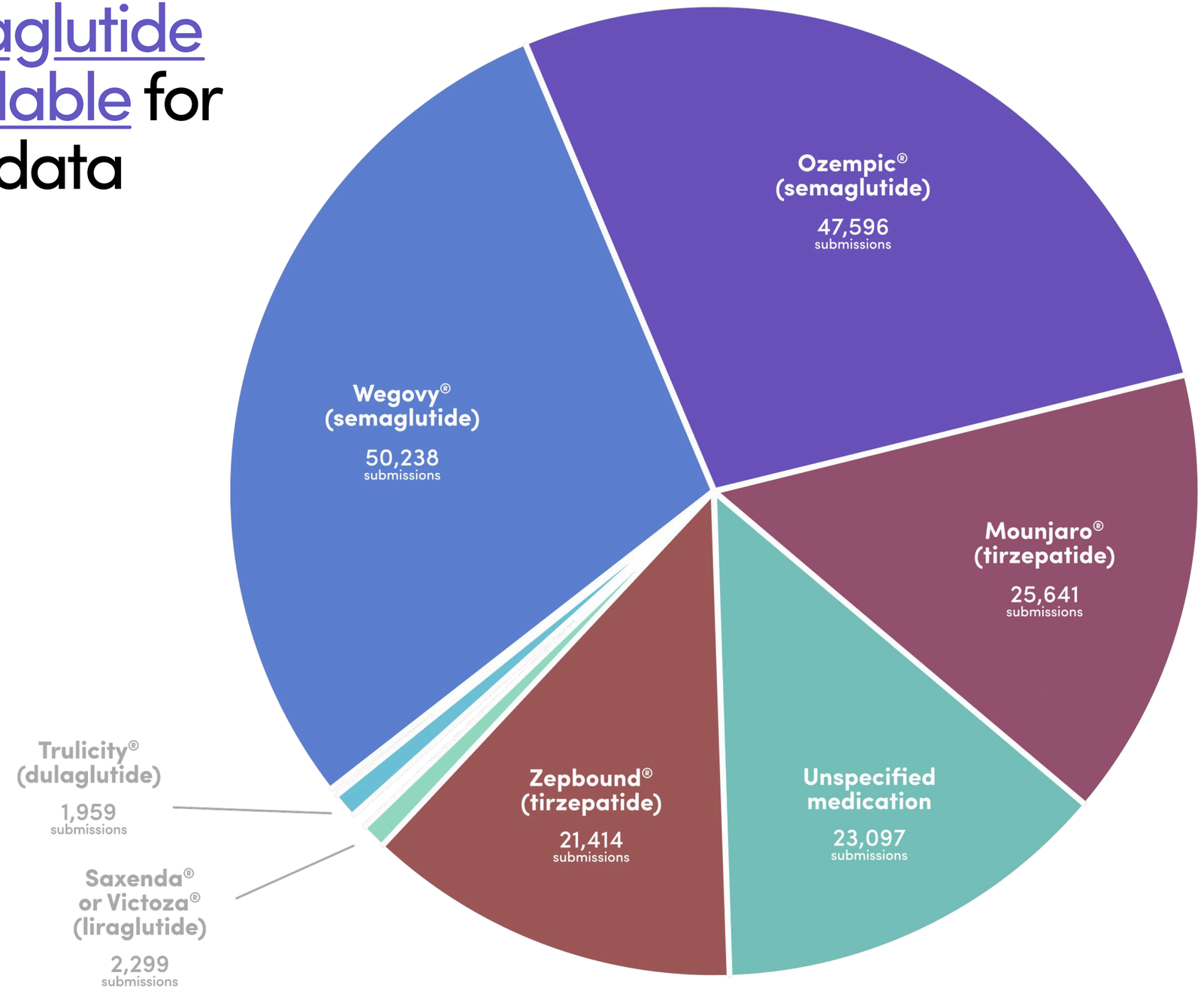
Over 172,000 people have reported an inability to access name brand GLP-1s

Hims & Hers initiated data collection on September 1, 2024, and as of December 14, 2024 has received 172,243 reports from individuals across the United States indicating they have been unable to obtain name brand GLP-1s.



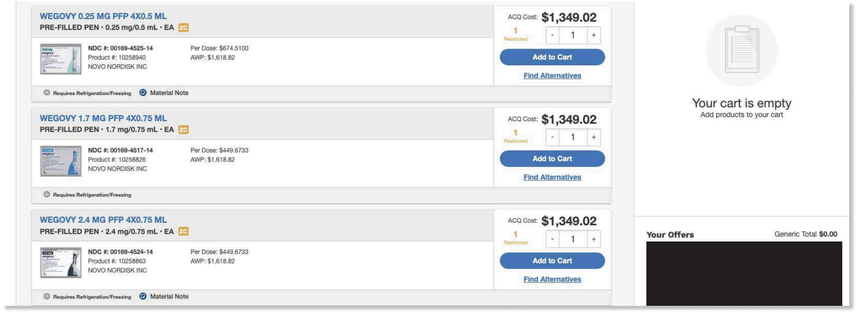
hims & hers

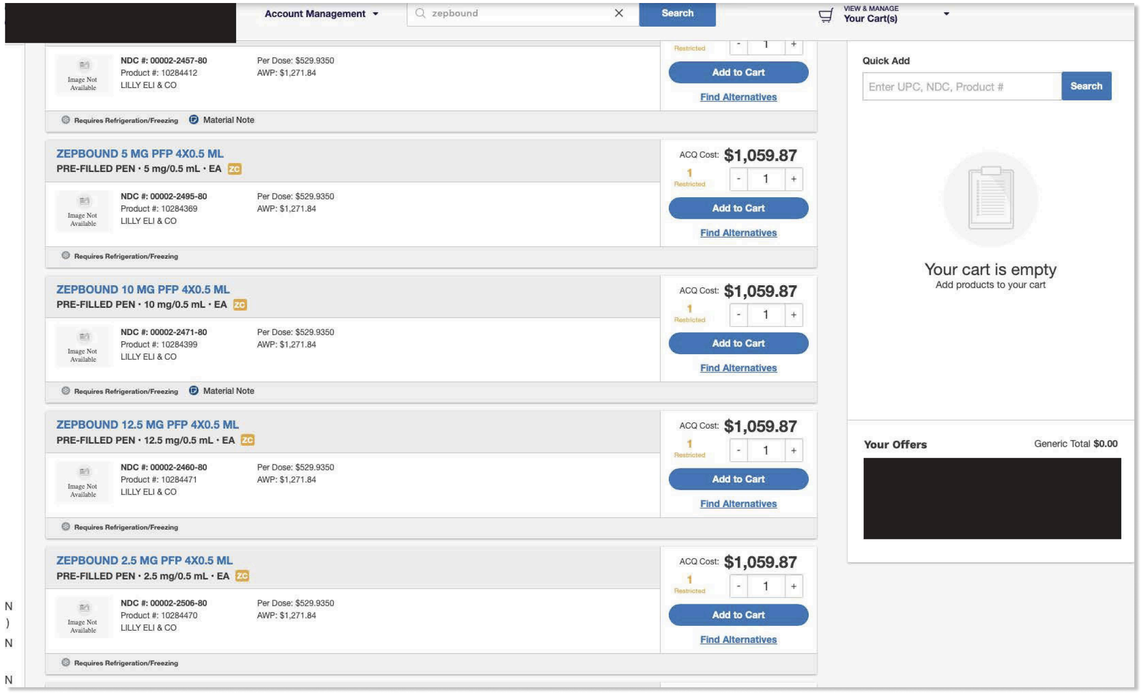
Tirzepatide and semaglutide remain widely unavailable for consumers reporting data through our platform

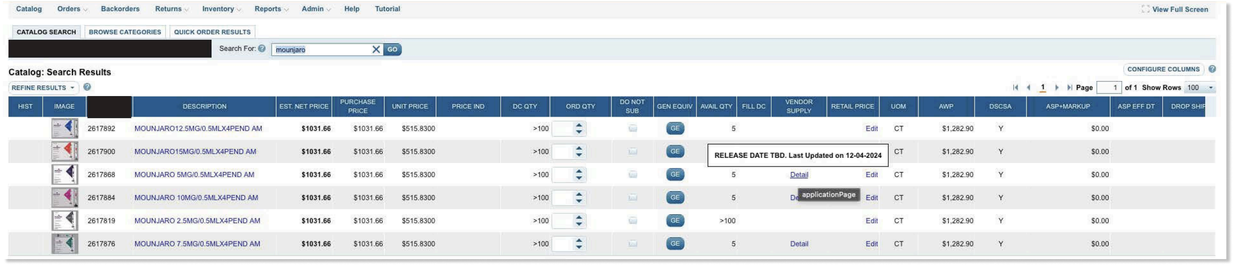


hims & hers

Our affiliated pharmacies continue to struggle to source branded GLP-1s across our leading wholesale partners







Supplier data as of 11/12/2024

hims & hers